

Integrating Health Care for
Sexual and Reproductive Health and Chronic Diseases

Comprehensive Cervical Cancer Control

A guide to essential practice



World Health
Organization

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ABBREVIATIONS AND ACRONYMS USED IN THIS GUIDE

AGC	atypical glandular cells
AIDS	acquired immunodeficiency syndrome
AIS	adenocarcinoma in situ
ANC	antenatal care
ASC-H	atypical squamous cells: cannot exclude a high-grade squamous intra-epithelial lesion
ASC-US	atypical squamous cells of undetermined significance
CHW	community health worker
CIN	cervical intraepithelial neoplasia
CIS	carcinoma in situ
CT	computerized tomography
DNA	deoxyribonucleic acid
EBRT	external beam radiotherapy
ECC	endocervical curettage
FAQ	frequently asked question
FIGO	International Federation of Gynecology and Obstetrics
FP	family planning
HBC	home-based care
HDR	high dose rate
HIV	human immunodeficiency virus
HPV	human papillomavirus
HSIL	high-grade squamous intraepithelial lesion
HSV	herpes simplex virus
IEC	information, education and communication
IUD	intrauterine device
LDR	low dose rate
LEEP	loop electrosurgical excision procedure
LLETZ	large loop excision of the transformation zone
LSIL	low-grade squamous intraepithelial lesion
MRI	magnetic resonance imaging

NCCP	national cancer control programme
NSAID	nonsteroidal anti-inflammatory drug
OC	oral contraceptives
PHC	primary health care
PID	pelvic inflammatory disease
PS	practice sheet
RTI	reproductive tract infection
SCJ	squamocolumnar junction
SIL	squamous intraepithelial lesion
STI	sexually transmitted infection
VIA	visual inspection with acetic acid
VILI	visual inspection with Lugol's iodine

PREFACE

Cancer is being diagnosed more and more frequently in the developing world. The recent World Health Organization report, *Preventing chronic diseases: a vital investment*, projected that over 7.5 million people would die of cancer in 2005, and that over 70% of these deaths would be in low- and middle-income countries. The importance of the challenge posed by cancer was reiterated by the World Health Assembly in 2005, in Resolution 58.22 on Cancer Prevention and Control, which emphasized the need for comprehensive and integrated action to stop this global epidemic.

Cervical cancer is the second most common type of cancer among women, and was responsible for over 250 000 deaths in 2005, approximately 80% of which occurred in developing countries. Without urgent action, deaths due to cervical cancer are projected to rise by almost 25% over the next 10 years. Prevention of these deaths by adequate screening and treatment (as recommended in this Guide) will contribute to the achievement of the Millennium Development Goals.

Most women who die from cervical cancer, particularly in developing countries, are in the prime of their life. They may be raising children, caring for their family, and contributing to the social and economic life of their town or village. Their death is both a personal tragedy, and a sad and unnecessary loss to their family and their community. Unnecessary, because there is compelling evidence – as this Guide makes clear – that cervical cancer is one of the most preventable and treatable forms of cancer, as long as it is detected early and managed effectively.

Unfortunately, the majority of women in developing countries still do not have access to cervical cancer prevention programmes. The consequence is that, often, cervical cancer is not detected until it is too late to be cured. An urgent effort is required if this situation is to be corrected. All women have a right to accessible, affordable and effective services for the prevention of cervical cancer. These services should be delivered as part of a comprehensive programme to improve sexual and reproductive health. Moreover, a concerted and coordinated effort is required to increase community awareness about screening for the prevention and detection of cervical cancer.

A great deal of experience and evidence-based knowledge is available for the prevention (and treatment) of cervical cancer and related mortality and morbidity. However, until now, this information was not available in one easy-to-use guide. This publication – produced by WHO and its partners – is designed to provide comprehensive practical advice to health care providers at all levels of the health care system on how to prevent, detect early, treat and palliate cervical cancer. In particular, the Guide seeks to ensure that health care providers at the primary and secondary levels will be empowered to use the best available knowledge in dealing with cervical cancer for the benefit of the whole community.

We call on all countries that have not already done so to introduce effective, organized control programmes for cervical cancer as recommended in this Guide. Together, we can significantly reduce the heavy burden of this disease and its consequences.

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INTRODUCTION

ABOUT THE GUIDE

Scope and objectives of the Guide

This Guide is intended to help those responsible for providing services aimed at reducing the burden posed by cervical cancer for women, communities and health systems. It focuses on the knowledge and skills needed by health care providers, at different levels of care, in order to offer quality services for prevention, screening, treatment and palliation of cervical cancer. The Guide presents guidelines and up-to-date, evidence-based recommendations covering the full continuum of care. Key recommendations are included in each chapter; a consolidated list is given on pages 11–12.

The four levels of care referred to throughout this Guide are:

- the community;
- the health centre or primary care level;
- the district hospital or secondary care level;
- the central or referral hospital or tertiary care level.

A detailed description of each level is given on page 9.

The Guide does not cover programme management, resource mobilization, or the political, legal and policy-related activities associated with cervical cancer control.

Adaptation

This Guide provides broadly applicable recommendations and may need to be adapted to local health systems, needs, language and culture. Information and suggestions on adaptation are available elsewhere (see list of additional resources). The Guide and its recommendations can also be used as a basis for introducing or adapting national protocols, and for modifying policies and practices.

The target audience

This Guide is intended primarily for use by health care providers working in cervical cancer control programmes in health centres and district hospitals in settings with limited resources. However, it may also be of interest to community and tertiary-level providers, as well as workers in other settings where women in need of screening or treatment might be reached.

The health care team

In an ideal cervical cancer control programme, providers work as a team, performing in a complementary and synergistic manner, and maintaining good communication within

and between levels. In some countries, the private and the nongovernmental sectors are important providers of services for cervical cancer. Providers in these sectors should be integrated in the health care team where relevant. Some possible roles of health care providers at different levels of the health care system are as follows:

- Community health workers (CHWs) may be involved in raising awareness of cervical cancer in the community, motivating and assisting women to use services, and following up those who have been treated at higher levels of care when they return to their community.
- Primary-health care providers can promote services and conduct screening and follow-up, and refer women to higher levels as necessary.
- District-level providers perform a range of diagnostic and treatment services, and refer patients to higher and lower levels of care.
- Central-level providers care for patients with invasive and advanced disease, and refer them back to lower levels, when appropriate.

Using the Guide

This Guide can be used by health care providers, supervisors and trainers:

- as a reference manual, providing basic, up-to-date information about prevention, screening, diagnosis and treatment of cervical cancer;
- to design preservice and in-service education and training, and as a self-education tool;
- as a review of prevention and management of cervical cancer;
- to find evidence-based advice on how to handle specific situations;
- to understand how the roles of different providers are linked with each other at the various levels of the health care system.

The Guide can be used as a whole, or users can focus on the sections that are relevant to their practice. Even if it is used selectively, we strongly recommend that readers should review the recommendations appearing on pages 11–12 in their entirety.

The contents

The Guide is composed of seven chapters and associated practice sheets, nine annexes and a glossary.

Each *chapter* includes:

- a description of the role and responsibilities of first- and second-level providers in relation to the specific topic of the chapter;
- a story illustrating and personalizing the topic of the chapter;

- essential background information on the subject of the chapter, followed by discussion of established and evolving practices in clinical care, and recommendations for practice, as appropriate;
- information on services at each of the four levels of the health care system;
- counselling messages to help providers communicate with women about the services they have received and the follow-up they will need;
- a list of additional resources.

Most of the chapters have associated *practice sheets*. These are short, self-contained documents containing key information on specific elements of care that health care providers may need to deliver, for example, how to take a Pap smear or how to perform cryotherapy. Counselling is included as an integral part of each procedure described. Practice Sheets 13–17 relate to procedures carried out by specialists. The information provided in these sheets can help other health care providers to explain the procedure to the patient, to counsel her, and to treat particular problems that may arise after the intervention.

The practice sheets can be individually copied or adapted.¹

The *annexes* detail specific practice components, using internationally established protocols (e.g. management flowcharts and treatment protocols) and strategies to enhance service quality (e.g. infection prevention).

The *glossary* contains definitions of scientific and technical terms used in the Guide.

Key principles and framework for this document

Principles

The approach of this Guide is based on the following principles:

- the right of everyone to equitable, affordable and accessible health care;
- reproductive health rights, as formulated in the Programme of Action adopted at the 1994 International Conference on Population and Development in Cairo (paragraph 7.6);
- the ethical principles of justice, autonomy and beneficence as defined and discussed in the Declaration of Helsinki and the International Ethical Guidelines for Biomedical Research Involving Human Subjects prepared by the Council of International Organizations of Medical Sciences (CIOMS) and WHO;

¹ The practice sheets are not intended to be used by a novice to learn how to carry out a procedure. They are intended as job aids, to remind trained providers of the essential steps and to help them to educate, counsel and correctly explain services to women and their families. They can also be used as a checklist to document competency as part of supportive supervision.

- a gender-based perspective: the discussion considers gender-related factors that may affect the power balance between men and women, reduce women's power of self-determination, and affect the provision and receipt of services.

Underlying framework

The following assumptions and context underlie the presentation of material in this Guide:

- All the interventions recommended are based on sound scientific evidence.
- Comprehensive control of cervical cancer should be undertaken in the context of a national cancer control programme (NCCP).
- Cervical cancer control should, as far as possible, be integrated into existing sexual and reproductive health services at the primary health care level.
- Screening and early diagnosis will lead to reduced morbidity and mortality only if they are integrated with follow-up and management of all preinvasive lesions and invasive cancers detected.
- Resources are available or will be developed to strengthen health infrastructure, and make available the following:
 - well trained providers;
 - necessary equipment and supplies;
 - a functional referral system and communication between different teams, services, health system levels and the community;
 - a quality assurance system.

The Guide's development

Evidence for the information in the Guide is based on the following:

- a review of the relevant literature;
- input from a Technical Advisory Group (TAG), consisting of experts in different disciplines from developing and developed countries, who elaborated and reviewed the Guide;
- extensive written review of drafts by a large number of external experts;
- review by WHO staff;
- information provided by the International Agency for Research on Cancer (IARC), including the handbook, *Cervix cancer screening*, published in 2005;
- in-country review (pre-field-testing) in six countries.

The evidence base for all the guidance presented in this Guide will be published separately as a companion document.

LEVELS OF THE HEALTH CARE SYSTEM²

In the community



COMMUNITY LEVEL

Includes individuals and organizations; community-based, faith-based and other nongovernmental organizations; and community and home-based palliative care services. Also included are health posts or “cases de santé”, usually staffed by an auxiliary nurse or community health worker.

At the health centre



HEALTH CENTRE – PRIMARY CARE LEVEL

Refers to primary care facilities with trained staff and regular working hours. Maternity and minimal laboratory services may be available.

Providers at this level include nurses, auxiliary nurses or nursing assistants, counsellors, health educators, medical assistants, clinical officers and, sometimes, physicians.

At the district hospital



DISTRICT HOSPITAL – SECONDARY CARE LEVEL

Typically, a hospital that provides general medical, paediatric, and maternity services, limited surgical care, inpatient and outpatient care, and, sometimes, intermittent specialized care. Patients may be referred from health centres and private practitioners in the district. Laboratory services may include cytology and histopathology.

Providers include generalist physicians or clinical officers, nurses, pharmacy technicians or dispensing clerks, medical assistants, nurse assistants, and laboratory technology assistants, possibly a gynaecologist and a cytotechnologist. Private and mission hospitals are often present at this level.

At the central hospital



CENTRAL OR REFERRAL HOSPITAL – TERTIARY CARE LEVEL

Tertiary care hospitals provide general and specialized care for complex cases and acutely ill patients, including surgery, radiotherapy and multiple outpatient and inpatient services. General medical, acute and chronic care clinics are offered. The most complete public-sector diagnostic and reference laboratory services are available with pathologists and cytotechnologists, radiology, and diagnostic imaging.

Providers may include gynaecologists, oncologists and radiotherapists, as well as those present at lower levels of care.

² This description does not include services and providers outside the formal health system: traditional healers, traditional birth attendants, medicine sellers, etc., who also play important roles.

ESSENTIAL READING

- Alliance for Cervical Cancer Prevention. *Planning and implementing cervical cancer prevention programs: a manual for managers*. Seattle, WA, 2004.
- IARC. *Cervix cancer screening*. Lyon, IARCPress, 2005 (IARC Handbooks of Cancer Prevention, Vol. 10).
- WHO. *Cervical cancer screening in developing countries*. Report of a WHO Consultation. Geneva, 2002.
- WHO. *Comprehensive cervical cancer control. A guide for essential practice, evidence base*. Geneva (in preparation).
- Alliance for Cervical Cancer Prevention (www.alliance-cxca.org).
- International Agency for Research on Cancer (www.iarc.fr).
- Program for Appropriate Technology in Health (www.path.org).
- EngenderHealth (www.engenderhealth.org).
- JHPIEGO (www.JHPIEGO.org).
- *Cancer prevention and control*. Resolution 58.22 of the 58th World Health Assembly (www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_22-en.pdf).
- WHO Cancer Control Programme (www.who.int/cancer).
- WHO Department on Reproductive Health and Research (www.who.int/reproductive-health).

WHO RECOMMENDATIONS

- Health education should be an integral part of comprehensive cervical cancer control.
- Cytology is recommended for large-scale cervical cancer screening programmes, if sufficient resources exist.

Recommended target ages and frequency of cervical cancer screening:

- New programmes should start screening women aged 30 years or more, and include younger women only when the highest-risk group has been covered. Existing organized programmes should not include women less than 25 years of age in their target populations.
- If a woman can be screened only once in her lifetime, the best age is between 35 and 45 years.
- For women over 50 years, a five-year screening interval is appropriate.
- In the age group 25-49 years, a three-year interval can be considered if resources are available.
- Annual screening is not recommended at any age.
- Screening is not necessary for women over 65 years, provided the last two previous smears were negative.
- Visual screening methods (using acetic acid (VIA) or Lugol's iodine (VILI)), at this time, are recommended for use only in pilot projects or other closely monitored settings. These methods should not be recommended for postmenopausal women.
- Human papillomavirus (HPV) DNA tests as primary screening methods, at this time, are recommended for use only in pilot projects or other closely monitored settings. They can be used in conjunction with cytology or other screening tests, where sufficient resources exist. HPV DNA-based screening should not begin before 30 years of age.
- There is no need to limit the use of hormonal contraceptives, despite the small increased risk of cervical cancer noted with use of combined oral contraceptives.
- Women should be offered the same cervical cancer screening and treatment options irrespective of their HIV status.
- Colposcopy is recommended only as a diagnostic tool and should be performed by properly trained and skilled providers.

continued next page

- Precancer should be treated on an outpatient basis whenever possible. Both cryotherapy and the loop electrosurgical excision procedure (LEEP) may be suitable for this purpose, depending on eligibility criteria and available resources.
- Histological confirmation of cervical cancer and staging must be completed before embarking on further investigations and treatment.
- Surgery and radiotherapy are the only recommended primary treatment modalities for cervical cancer.
- Brachytherapy is a mandatory component of curative radiotherapy of cervical cancer.
- Surgery for treatment of cervical cancer should be performed only by surgeons with focused training in gynaecological cancer surgery.
- The needs of women with incurable disease should be addressed by using existing palliative care services or establishing new ones. Providers at all care levels need to be trained and must have the resources necessary to manage the most common physical and psychosocial problems, with special attention to pain control.
- A comprehensive cervical cancer programme should ensure that opioid, non-opioid and adjuvant analgesics, particularly morphine for oral administration, are available.

1

CHAPTER 1: BACKGROUND

CHAPTER 1: BACKGROUND

Key points

- Cervical cancer is one of the leading causes of cancer death in women in the developing world.
- The primary underlying cause of cervical cancer is infection with human papillomavirus (HPV), a very common virus that is sexually transmitted.
- Most HPV infections resolve spontaneously; those that persist may lead to the development of precancer and cancer.
- It usually takes 10 to 20 years for precursor lesions caused by HPV to develop into invasive cancer.
- Effective interventions against cervical cancer exist, including screening for, and treatment of, precancer and invasive cancer.
- An estimated 95% of women in developing countries have never been screened for cervical cancer.
- Over 80% of women newly diagnosed with cervical cancer live in developing countries; most are diagnosed when they have advanced disease.
- The cure rate for invasive cervical cancer is closely related to the stage of disease at diagnosis and the availability of treatment. If left untreated, cervical cancer is almost always fatal.
- Because of its complexity, cervical cancer control requires a team effort and communication between health care providers at all levels of the health care system.

ABOUT THIS CHAPTER

Cancer control programmes can go a long way in preventing cervical cancer and reducing its morbidity and mortality. This chapter explains why organized cervical cancer control programmes are urgently needed. It outlines the burden that the disease places on women and on health services, summarizing global statistics and describing regional and intracountry inequities. The chapter also describes essential elements of successful programmes, including the rationale for selection of the target group for screening, as well as barriers to their implementation, concluding that cancer control needs to be based on a constant team effort.

WHY FOCUS ON CERVICAL CANCER?

In 2005, there were, according to WHO projections, over 500 000 new cases of cervical cancer, of which over 90% were in developing countries. It is estimated that over 1 million women worldwide currently have cervical cancer, most of whom have not been diagnosed, or have no access to treatment that could cure them or prolong their life. In 2005, almost 260 000 women died of the disease, nearly 95% of them in developing countries, making cervical cancer one of the gravest threats to women's lives. In many developing countries, access to health services is limited and screening for cervical cancer either is non-existent or reaches few of the women who need it. In these areas, cervical cancer is the most common cancer in women and the leading cause of cancer death among women.

The primary underlying cause of cervical cancer is infection with one or more high-risk types of the human papillomavirus (HPV), a common virus that is sexually transmitted. Most new HPV infections resolve spontaneously; if it persists, infection may lead to the development of precancer which, left untreated, can lead to cancer. As it usually takes 10–20 years for precursor lesions caused by HPV to develop into invasive cancer, most cervical cancers can be prevented by early detection and treatment of precancerous lesions.

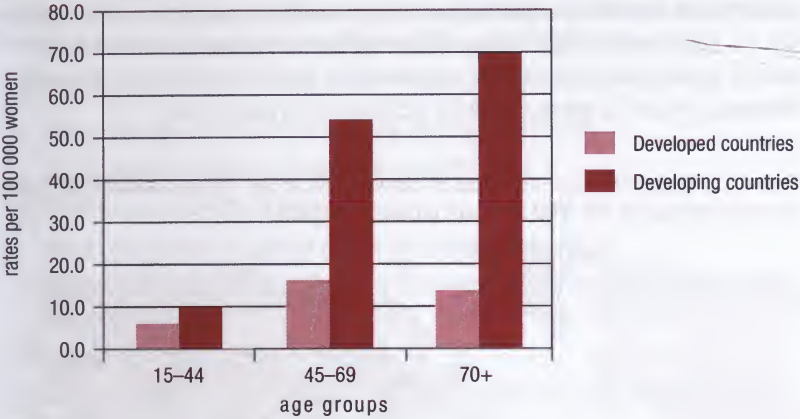
Experience in developed countries has shown that well planned, organized screening programmes with high coverage can significantly reduce the number of new cases of cervical cancer and the mortality rate associated with it. There is also evidence that general awareness about cervical cancer, effective screening programmes, and the improvement of existing health care services can reduce the burden of cervical cancer for women and for the health care system. There is a huge difference in the incidence of, and mortality from, cervical cancer between developed and developing countries, as shown in Figures 1.1 and 1.2.

The main reasons for the higher incidence and mortality in developing countries are:

- lack of awareness of cervical cancer among the population, health care providers and policy-makers;
- absence or poor quality of screening programmes for precursor lesions and early-stage cancer. In women who have never been screened, cancer tends to be diagnosed in its later stages, when it is less easily treatable;
- limited access to health care services;
- lack of functional referral systems.

The difference between developed and developing countries reflects stark inequalities in health status, and represents a challenge for health services.

Figure 1.1 Age-standardized Incidence rates of cervical cancer in developed and developing countries (2005)



Source: WHO. *Preventing chronic diseases: a vital investment*. Geneva, 2005.

Figure 1.2 Age-standardized mortality rates of cervical cancer in developed and developing countries (2005)

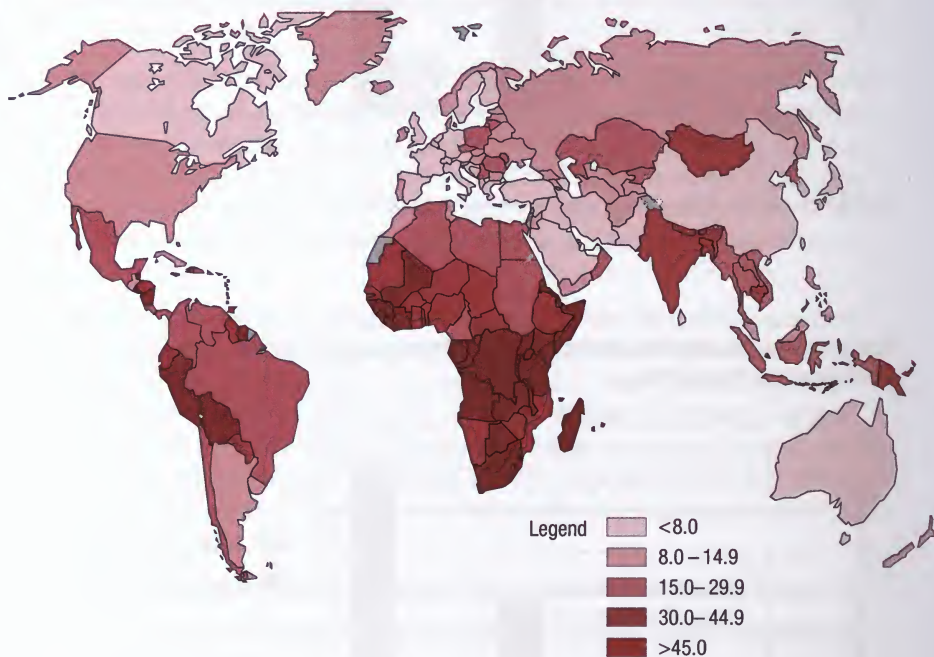


Source: WHO. *Preventing chronic diseases: a vital investment*. Geneva, 2005.

WHO IS MOST AFFECTED BY CERVICAL CANCER?

Cervical cancer is rare in women under 30 years of age and most common in women over 40 years, with the greatest number of deaths usually occurring in women in their 50s and 60s. Cervical cancer occurs worldwide, but the highest incidence rates are found in Central and South America, eastern Africa, South and South-East Asia, and Melanesia. Figure 1.3 shows the global incidence of cervical cancer.

Figure 1.3 Worldwide incidence rates of cervical cancer per 100,000 females (all ages), age-standardised to the WHO standard population (2005)



Over the past three decades, cervical cancer rates have fallen in most of the developed world, probably as a result of screening and treatment programmes. In contrast, rates in most developing countries have risen or remained unchanged. Inequalities also exist in the developed world, where rural and poorer women are at greatest risk of invasive cervical cancer.

Left untreated, invasive cervical cancer is almost always fatal, causing enormous pain and suffering for the individual and having significant adverse effects on the welfare of their families and communities.

BARRIERS TO CONTROL OF CERVICAL CANCER

A number of countries have implemented cervical cancer control programmes in recent decades; some of these have produced significant decreases in incidence and mortality, while others have not. Among the reasons for failure are the following:

- Political barriers:
 - lack of priority for women's sexual and reproductive health;
 - lack of national policies and appropriate guidelines.
- Community and individual barriers:
 - lack of awareness of cervical cancer as a health problem;
 - attitudes, misconceptions and beliefs that inhibit people discussing diseases of the genital tract.
- Economic barriers (lack of resources).
- Technical and organizational barriers, caused by poorly organized health systems and weak infrastructure.

Lack of priority for women's health

The lack of priority given to women's health needs, particularly those not related to maternity and family planning, was a focus of the International Conference on Population and Development, held in Cairo in 1994. At this Conference, countries made strong commitments to reframe women's health in terms of human rights and to promote an integrated vision of reproductive health care. Significant advances have occurred in some areas, but cervical cancer has still not received sufficient attention in many countries, despite its high incidence, morbidity and mortality.

Lack of evidence-based national guidelines

National guidelines for cervical cancer control may not exist or may not reflect recent evidence and local epidemiological data. Generic guidelines, available in the literature, are often not used or not adapted to local needs. In many programmes, scarce resources are wasted in screening young women attending family planning and antenatal clinics, and in screening more frequently than necessary. Resources would be better used to reach older women, who are at greater risk and who generally do not attend health services.

Poorly organized health systems and infrastructure

A well functioning health system, with the necessary equipment and trained providers, is essential for prevention activities, screening, diagnosis, linkages for follow-up and treatment, and palliative care.

Lack of awareness

In many places, cervical cancer has been ignored by decision-makers, health care providers and the population at large. Decision-makers may not be aware of the tremendous burden of disease and magnitude of the public health problem caused by this cancer. Providers may lack accurate information on its natural history, detection and treatment. Many women and men have not heard of cervical cancer and do not recognize early signs and symptoms when they occur. Women at risk may not be aware of the need to be tested, even when they do not have any symptoms.

Attitudes, misconceptions and beliefs

Attitudes and beliefs about cervical cancer among the general population and health care providers can also present barriers to its control. Cancer is often thought to be an untreatable illness, leading inevitably to death. In addition, the female genital tract is often considered private and women may be shy about discussing symptoms related to it. This is especially true in settings where the health care provider is a man, or is from a different culture. Destigmatizing discussion of the female genital tract may be an important strategy in encouraging women to be screened and to seek care if they have symptoms suggestive of cervical cancer.

Lack of resources

In the vast majority of settings where competition for limited funds is fierce, cervical cancer has remained low on the agenda. In these settings, cervical cancer is often not considered a problem or a funding priority.

THE FOUR COMPONENTS OF CERVICAL CANCER CONTROL

Within a national cancer control programme, there are four basic components of cervical cancer control:

- primary prevention;
- early detection, through increased awareness and organized screening programmes;
- diagnosis and treatment;
- palliative care for advanced disease.

Primary prevention means prevention of HPV infection and cofactors known to increase the risk of cervical cancer, and includes:

- education and awareness-raising to reduce high-risk sexual behaviours;
- implementation of locally appropriate strategies to change behaviour;

- the development and introduction of an effective and affordable HPV vaccine;
- efforts to discourage tobacco use, including smoking (which is a known risk factor for cervical and other cancers).

Early detection includes:

- organized screening programmes, targeting the appropriate age group and with effective links between all levels of care;
- education for health care providers and women in the target group, stressing the benefits of screening, the age at which cervical cancer most commonly occurs, and its signs and symptoms.

Diagnosis and treatment includes:

- follow-up of patients who are positive on screening, to ensure that a diagnosis is made and the disease appropriately managed;
- treatment of precancer, using relatively simple procedures, to prevent the development of cancer;
- treatment of invasive cancer, including surgery, radiotherapy and chemotherapy.

Palliative care includes:

- symptomatic relief for bleeding, pain and other symptoms of advanced cancer and for the side-effects caused by some treatments;
- compassionate general care for women whose cancer cannot be cured;
- involvement of the family and the community in caring for cancer patients.

Cervical cancer control can be achieved if:

- A national policy on cervical cancer control exists, based on the natural history of the disease and on local prevalence and incidence in different age groups.
- Financial and technical resources are allocated to support the policy.
- Programmes of public education and advocacy for prevention are in place to support national policies.
- Screening is organized, rather than opportunistic, and follow-up and quality control are assured (see Chapter 4).
- The largest possible number of women in the target group are screened.
- Screening services are linked to treatment of precancer and invasive cancer.
- A health information system is in place to monitor achievements and identify gaps.

A TEAM APPROACH TO CERVICAL CANCER CONTROL

Because of its complexity, cervical cancer control requires a multidisciplinary team effort and communication between providers at all levels of the health care system.

- Community health workers (CHWs) need to communicate with nurses and physicians from primary health care settings, and sometimes with laboratory personnel and specialists at the district and central levels.
- Communication within and between health facilities, and links with community-based workers, are essential to coordinate services, to give women the best possible care, and to improve outcomes. Two-way communication is particularly important for the management of women with invasive cancer, who are treated in hospital and then return to the community to recover or to be cared for.
- Secondary and tertiary care providers, such as surgeons, radiotherapists and nurses, need to communicate in plain language with primary care providers and CHWs. It can be helpful, for example, for central hospital-based physicians to go to communities from time to time to talk with CHWs and to see for themselves the problems in low-resource settings of caring for women who have been treated for cancer.
- Facility managers and supervisors can foster links by communicating with providers, and by monitoring and improving the quality of the existing system.
- Managers must ensure that supplies are available and that there are adequate incentives for good work.
- The cervical cancer control team must obtain the support and commitment of regional and national decision-makers.

Tips for building a team

- Ensure good communication between team members through regular meetings where information is exchanged and staff can air and solve work-related problems.
- Foster mutual trust and caring among staff, including supervisors, to stimulate genuine interest in each other.
- Keep motivation high by providing training and support, with regular updates, supervision and mentoring.
- Ensure a pleasant, clean, safe work environment, with adequate supplies and staffing.
- Reward staff adequately for their work.

ADDITIONAL RESOURCES

- Alliance for Cervical Cancer Prevention. *Planning and implementing cervical cancer prevention programs: a manual for managers*. Seattle, WA, 2004.
- Alliance for Cervical Cancer Prevention Website: www.alliance-cxca.org.
- International Agency for Research on Cancer Website: www.iarc.fr.
- World Bank. *World development indicators 2003*. Washington, DC, 2003.
- World Health Organization. *National cancer control programmes*, 2nd ed. Geneva, 2002.

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CHAPTER 2: ANATOMY OF THE FEMALE PELVIS AND NATURAL HISTORY OF CERVICAL CANCER

CHAPTER 2: ANATOMY OF THE FEMALE PELVIS AND NATURAL HISTORY OF CERVICAL CANCER

Key points

- Basic knowledge of the anatomy of the female pelvis and the natural history of cervical cancer is essential for understanding the disease and communicating messages about prevention, screening, treatment and care.
- The cervix undergoes normal changes from birth until after the menopause.
- The cervical transformation zone is the area where the great majority of precancers and cancers arise.
- The transformation zone is larger during puberty and pregnancy and in women who have used oral contraceptives (OCs) for a long time, which may increase exposure to HPV. This may explain why early sexual activity, multiple pregnancies and, to a lesser extent, long-term use of OCs, are cofactors for the later development of cervical cancer.
- After the menopause, the transformation zone may extend into the inner cervical canal, requiring the use of an endocervical speculum to see it completely.
- From the time that mild dysplasia is identified, it usually takes 10 to 20 years for invasive cancer to develop; this means that cervical cancer control is possible through screening and treatment.
- HPV infection is a necessary, but not a sufficient, cause of cervical cancer; host factors, as well as behavioural and environmental factors, may facilitate cancer development.

ABOUT THIS CHAPTER

The natural history of cervical cancer, with its usually slow progression from early precancer to invasive disease, provides the rationale for screening, early detection and treatment. To understand how cervical precancer and cancer develop and progress, it is necessary to have a basic understanding of female pelvic anatomy, including the blood vessels, lymphatic drainage systems and nerve supply. This chapter describes the pelvic anatomy, and contains additional information for non-specialists on normal and abnormal changes that occur in the cervix and how these relate to screening and treatment for precancer and cancer. With this understanding, health care providers will be able to communicate accurate information on cervical cancer prevention, screening and management to women, patients, and their families.

ANATOMY AND HISTOLOGY

This section describes the female pelvic anatomy, the covering layers of the cervix or epithelia, and the normal physiological changes that take place during a woman's life cycle, and identifies the area most likely to develop precancerous abnormalities.

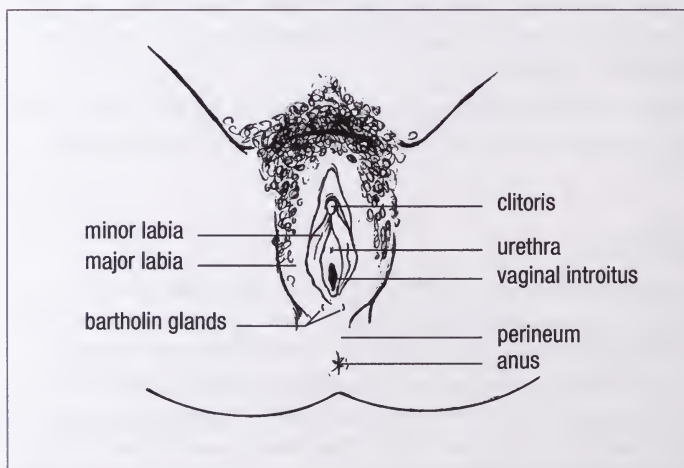
Female pelvic anatomy

An understanding of the anatomy of the female pelvic structures will help providers involved in cervical cancer programmes to:

- perform their tasks, including screening and diagnosis;
- interpret laboratory and treatment procedure reports and clinical recommendations received from providers at higher levels of the health care system;
- educate patients and families on their condition and plan for their follow-up;
- communicate effectively with providers at other levels of care.

The external genitalia

Figure 2.1 Female external genitalia

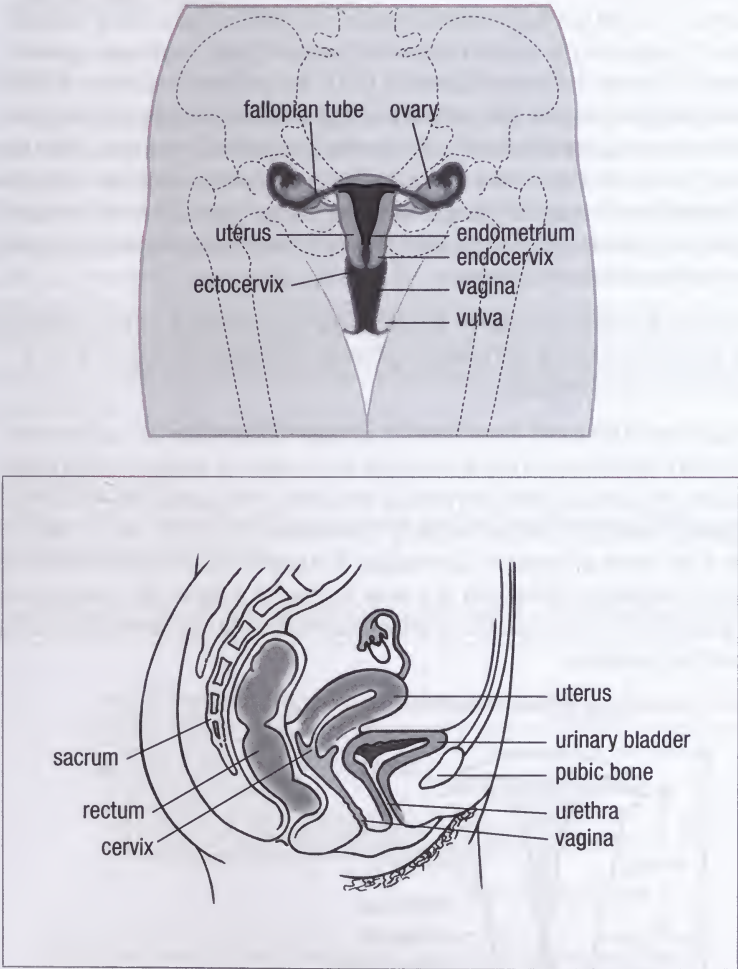


As seen in Figure 2.1, the external genitalia include the major and minor labia, the clitoris, the urinary opening (urethra), and the vaginal opening or introitus. The area between the vulva and the anus is called the perineum. Bartholin glands are two small bodies on either side of the introitus.

The internal organs

As shown in Figure 2.2, the vagina and uterus lie behind and above the pubic bone in the pelvis. The urinary bladder and urethra are in front of the vagina and uterus, and the rectum is behind them. The ureters (small tubes that deliver urine from the kidney to the bladder) lie close to the cervix on each side.

Figure 2.2 Front and side view of female internal organs



The vagina

The vagina is an elastic fibromuscular tube leading from the introitus to the cervix; its walls form multiple folds, allowing it to expand during sexual activity and childbirth. The walls of the vagina are normally in contact with each other. The lower portion of the cervix (ectocervix) protrudes into the upper end of the vagina and the vaginal area surrounding it comprises the anterior, posterior and lateral fornices.

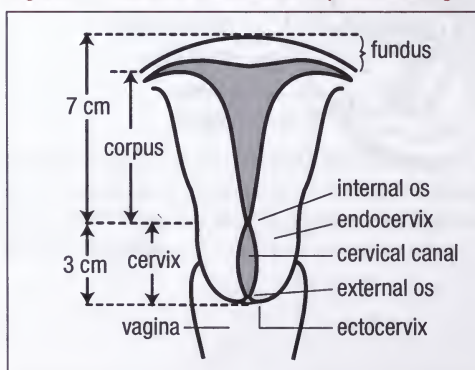
The uterus and cervix

The uterus or womb is a thick-walled, pear-shaped, hollow organ made of smooth muscle. It is supported by several connective tissue structures: transverse ligaments, uterosacral ligament and broad ligament (a fold in the peritoneum spanning the area between the uterus and the side walls of the bony pelvis which enfolds the fallopian tubes and round ligaments within it). The ovaries are attached to the back of the broad ligament. The cavity of the uterus is lined by the endometrium, a glandular epithelium which goes through dramatic changes with the menstrual cycle. When not enlarged by pregnancy or tumours, the uterus measures approximately 10 centimetres from its top (fundus) to the bottom of the cervix.

The cervix is the lower one-third of the uterus and is composed of dense, fibromuscular tissue (Figure 2.3) lined by two types of epithelium (see below). It is about 3 cm in length and 2.5 cm in diameter.

The lower part of the cervix (outer cervix or ectocervix) lies within the vagina and is visible with a speculum; the upper two-thirds (inner cervix or endocervix) lies above the vagina. The cervical canal runs through the centre of the cervix from the internal os (opening) leading into the uterine cavity to the external os, which can be seen in the centre of the cervix on speculum examination. The external os is seen as a small round opening in nulliparous women and as a wide, mouth-like, irregular slit in women who have given birth. The lower portion of the endocervical canal can be visualized using an endocervical speculum.

Figure 2.3 Uterus of a woman of reproductive age



The blood and lymph vessels

The arteries that supply the uterus and cervix derive from the internal iliac arteries and their uterine, cervical and vaginal branches. The cervical branches descend along the length of the cervix at the 3 and 9 o'clock positions. It is important to keep this in mind when injecting local anaesthetic, in order to avoid injecting into the artery. The veins draining the cervix run parallel to the arteries. The lymph nodes and ducts draining the pelvic organs lie close to the blood vessels and may act as a pathway for the spread of cervical cancer. In late stages of cancer, large tumours may block lymphatic drainage and cause the legs to swell (lymphoedema).

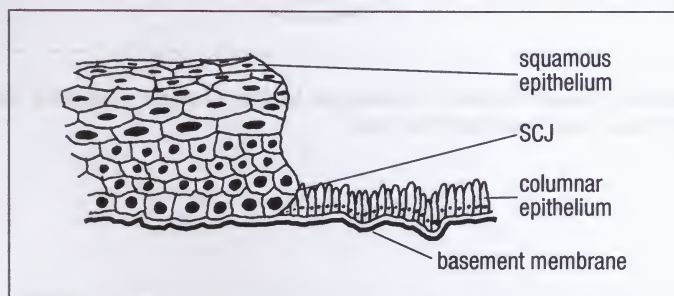
The nerves

The ectocervix has no pain nerve endings; thus, procedures involving only this area (biopsy, cryotherapy) are well tolerated without anaesthesia. The endocervix, on the other hand, is rich in sensory nerve endings, and is sensitive to painful stimuli, injury and stretching. Networks of nerve fibres are found around the cervix and extend to the body of the uterus. A paracervical block, to produce local anaesthesia for certain procedures, is performed by injecting anaesthetic at various points between the cervical epithelium and the vaginal tissue. Because sympathetic and parasympathetic nerves are also present, procedures involving the endocervical canal (such as insertion of an endocervical curette) may sometimes cause a vasovagal reaction (sweating, slow heart rate and fainting).

The cervical epithelia

The surface of the cervix is lined by two types of epithelium: squamous epithelium and columnar epithelium (Figure 2.4).

Figure 2.4 The two types of cervical epithelium and the squamocolumnar junction (SCJ)



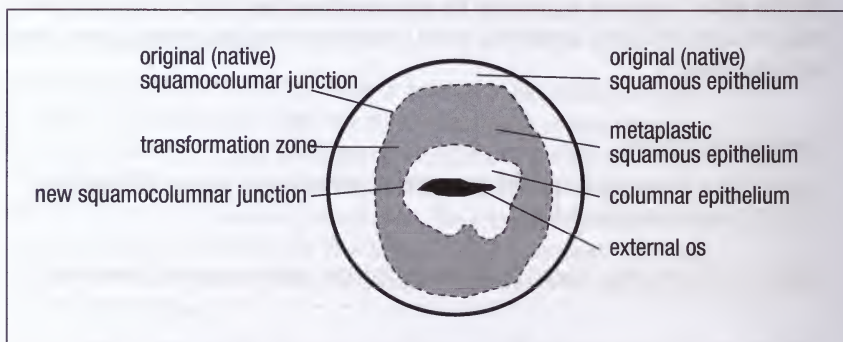
Adapted from: Sellors JW, Sankaranarayanan R. *Colposcopy and treatment of cervical intraepithelial neoplasia: a beginners' manual*. Lyon, France, IARCPress, 2002.

The stratified squamous epithelium is a multilayered epithelium of increasingly flatter cells. It normally covers most of the ectocervix and vagina and, in premenopausal women, appears pale pink and opaque. Its lowest (basal) layer, composed of rounded cells, is attached to the basement membrane, which separates the epithelium from the underlying fibromuscular stroma. In postmenopausal women, the squamous epithelium has fewer layers of cells, appears whitish-pink, and is prone to trauma, which is often visible as small haemorrhages or petechiae.

The columnar epithelium lines the cervical canal and extends outwards to a variable portion of the ectocervix. It consists of a single layer of tall cells sitting on the basement membrane. This layer is much thinner than the squamous lining of the ectocervix. When seen with an endocervical speculum, it appears shiny red.

The original squamocolumnar junction (SCJ) appears as a sharp line, with a step produced by the different thicknesses of the columnar and squamous epithelia. The location of the original SCJ varies with the woman's age, hormonal status, history of birth trauma, pregnancy status, and use of oral contraceptives (Figures 2.5 and 2.6).

Figure 2.5 The transformation zone of the cervix of a parous woman of reproductive age



Source: Sellors JW, Sankaranarayanan R. *Colposcopy and treatment of cervical intraepithelial neoplasia: a beginners' manual*. Lyon, France, IARCPress, 2002.

Squamous metaplasia and the transformation zone

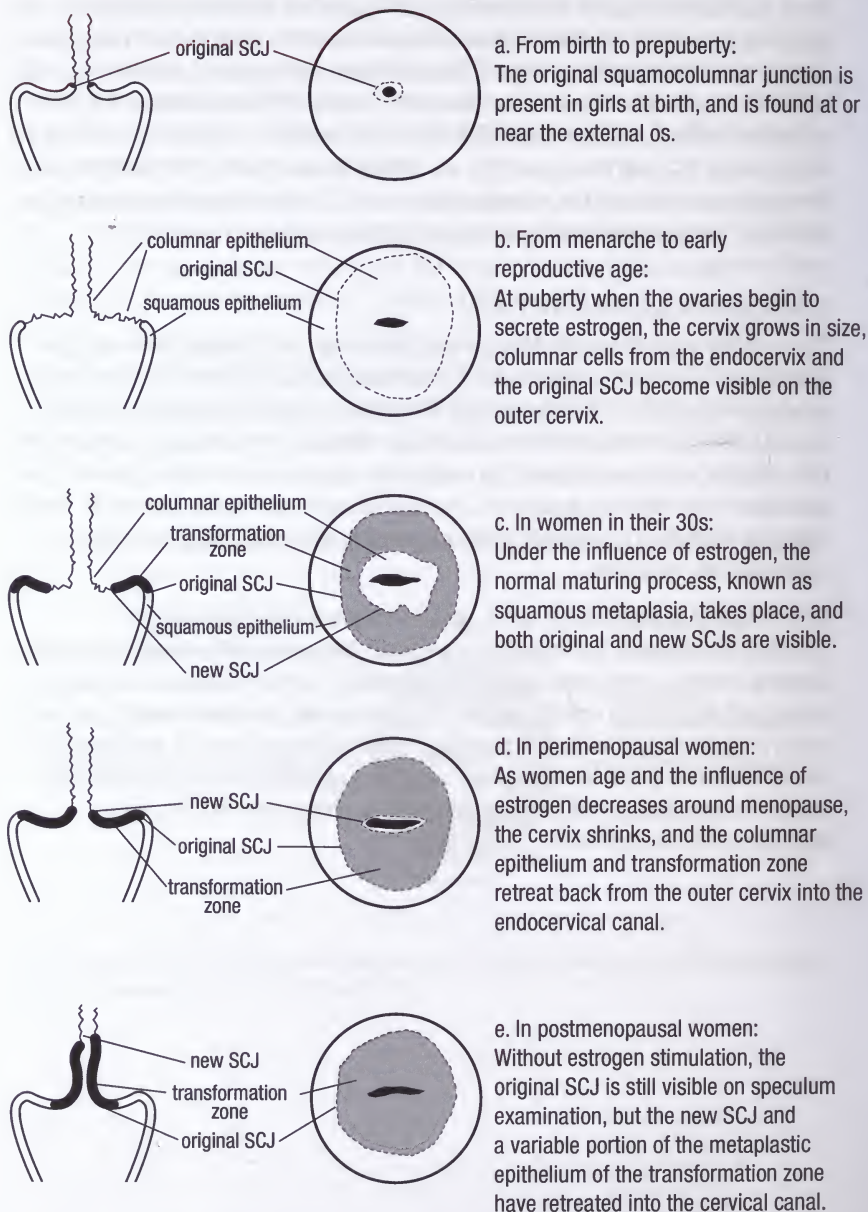
When exposed to the acidic environment of the vagina, the columnar epithelium is gradually replaced by stratified squamous epithelium, with a basal layer of polygonal-shaped cells derived from the original columnar cells. This normal replacement process is termed squamous metaplasia and gives rise to a new SCJ. When mature, the new squamous epithelium closely resembles the original squamous epithelium. However, the newly formed SCJ and the original SCJ are distinct on examination. The transformation zone is the area between the original and the new SCJ, where the columnar epithelium is being or has been replaced by squamous epithelium (Figures 2.5 and 2.6).

Development of precancer and cancer

The stratified squamous epithelium covering the cervix provides protection from toxic substances and infection. Under normal circumstances, the top layers are continually dying and sloughing off, and the integrity of the lining is maintained by the constant, orderly formation of new cells in the basal layer. However, in the presence of persistent HPV infection and other cofactors, the metaplastic squamous cells of the transformation zone take on an abnormal appearance, cervical squamous precancer (dysplasia). These cells later multiply in a disorderly manner typical of cancerous change to produce squamous cell carcinoma.

During puberty and pregnancy, and in women using oral contraceptives, the transformation zone on the ectocervix is enlarged. Exposure to HPV at such times may facilitate infection, which may explain the association between squamous cell cervical cancer and early sexual activity, multiple pregnancies and, to a lesser extent, long-term use of oral contraceptives. Ninety per cent of cervical cancer cases are squamous cell carcinomas arising from the metaplastic squamous epithelium of the transformation zone; the other 10% are cervical adenocarcinomas arising from the columnar epithelium of the endocervix.

Figure 2.6 The process of squamous metaplasia



Adapted from: Sellors JW, Sankaranarayanan R. *Colposcopy and treatment of cervical intraepithelial neoplasia: a beginners' manual*. Lyon, France, IARCPress, 2002.

NATURAL HISTORY OF CERVICAL CANCER

What is cancer?

Cancer is a term used for the malignant, autonomous and uncontrolled growth of cells and tissues. Such growth forms tumours, which may invade surrounding and distant parts of the body, destroying normal tissues and competing for nutrients and oxygen. Metastases occur when small groups of cells become detached from the original tumour, are carried to distant sites via the blood and lymph vessels, and start new tumours similar to the original one.

The development of cervical cancer

The primary cause of squamous cervical cancer is persistent or chronic infection with one or more of the so-called high-risk or oncogenic types of human papillomavirus. The most common cancer-causing types are 16 and 18, which are found in 70% of all cervical cancers reported. Other oncogenic types (e.g. 31, 33, 45, and 58) are found less commonly and may have different prevalence in different geographical areas. Low-risk HPV types 6 and 11 are not associated with cancer, but cause genital warts. The key determinants of HPV infection for both men and women are related to sexual behaviour, and include young age at sexual initiation, a high number of sexual partners, and having partners with multiple partners. High-risk HPV infection is most common in young women, with a peak prevalence as high as 25-30% in women under 25 years of age. In most sites, prevalence decreases sharply with age.

While infection with a high-risk HPV is the underlying cause of cervical cancer, most women infected with high-risk HPV do not develop cancer. Most cervical HPV infections, regardless of type, are short-lived, with only a small number persisting and even fewer progressing to precancerous lesions or invasive cancer. The conditions or cofactors that lead HPV infection to persist and progress to cancer are not well understood, but the following probably play a role.

- HPV-related cofactors:
 - viral type;
 - simultaneous infection with several oncogenic types;
 - high amount of virus (high virus load).

- Host-related cofactors
 - immune status: people with immunodeficiency (such as that caused by HIV infection) have more persistent HPV infections and a more rapid progression to precancer and cancer;
 - parity: the risk of cervical cancer increases with higher parity.
- Exogenous cofactors:
 - tobacco smoking;
 - coinfection with HIV or other sexually transmitted agents such as herpes simplex virus 2 (HSV-2), *Chlamydia trachomatis* and *Neisseria gonorrhoeae*;
 - long-term (> 5 years) use of oral contraceptives.

This last cofactor is of particular concern since limiting the use of oral contraceptives could have far-reaching effects on women's choice of contraceptive and hence on the rates of unwanted pregnancy, unsafe abortion and maternal mortality. A WHO expert group, convened to examine the evidence and formulate recommendations, concluded that all methods of contraception, including OCs, carry risks and benefits. With respect to cervical cancer, the benefits of OCs outweigh the risks, because the number of cervical cancers that result from their use is likely to be very small; therefore, women who choose to use OCs should not be prevented or discouraged from doing so.

RECOMMENDATION

There is no need to limit the use of hormonal contraceptives, despite the small increased risk of cervical cancer noted with use of combined oral contraceptives.

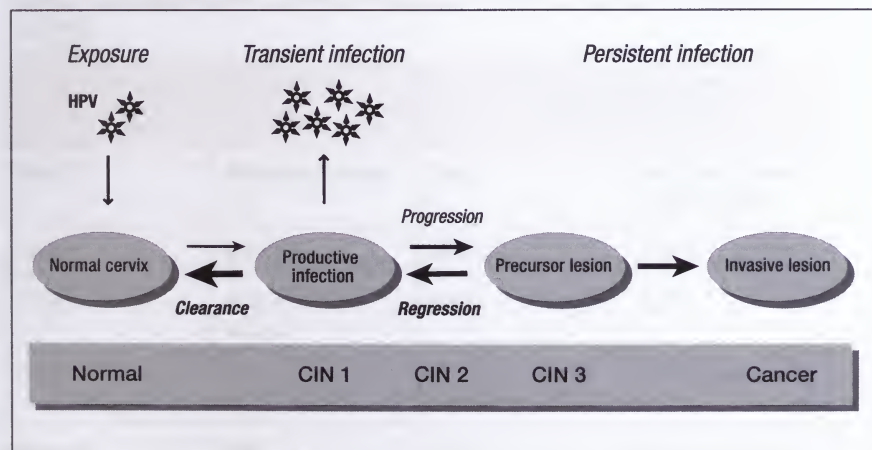
Natural history of precancer

During early adolescence and first pregnancy, when squamous metaplasia is occurring, infection with HPV may induce changes in the newly transformed cells, with viral particles being incorporated into the DNA of the cells. If the virus persists, it may cause precancerous and, later, cancerous changes by interfering with the normal control of cell growth (Figures 2.7 and 2.8).

Estimates of the time it takes for cancer to develop from HPV infection vary. Sixty per cent or more of cases of mild dysplasia resolve spontaneously and only about 10% progress to moderate or severe dysplasia within 2–4 years; in some cases, moderate or severe dysplasia may occur without an earlier detectable mild dysplasia stage. Less than 50% of cases of severe dysplasia progress to invasive carcinoma, with much lower rates seen in younger women.

The usual 10–20-year natural history of progression from mild dysplasia to carcinoma makes cervical cancer a relatively easily preventable disease and provides the rationale for screening.

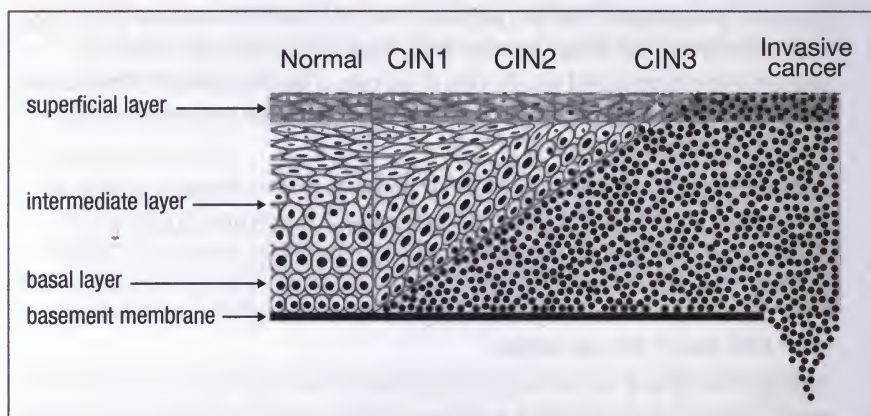
Figure 2.7 Natural history of cervical cancer



CIN: cervical intraepithelial lesion

Adapted from: *Cervix cancer screening*. Lyon, IARCPress, 2005 (IARC Handbooks of Cancer Prevention, Vol. 10).

Figure 2.8 Progress from normal epithelium to invasive cancer



CIN: cervical intraepithelial lesion

Precancer classification systems

There are many systems in use in different parts of the world for classifying and naming precancerous conditions of the cervix, based on cytology and histology (Table 2.1). Some are more useful than others because they incorporate knowledge of the disease's natural history acquired over the past few decades. The classification system of cervical intraepithelial neoplasia (CIN) evolved in 1968, to take into account the different natural histories seen with different degrees of dysplasia. It is still used in many countries for cytological reports, although strictly speaking it should only be used for histological reports (results of microscopic examination of tissue samples). The Bethesda system was developed in the 1990s at the United States National Cancer Institute. In this system, which should be used only for cytological reports, CIN 2 and 3 are combined into one group, termed high-grade squamous intraepithelial lesions (HSIL). Cytologically (i.e. on microscopic examination of a smear), it is difficult, if not impossible, to distinguish CIN 2 and 3. In the 2001 Bethesda classification, atypical cells are divided into ASC-US (atypical squamous cells of undetermined significance) and ASC-H (atypical squamous cells: cannot exclude a high-grade squamous epithelial lesion). This classification is recommended by WHO for cytological reports.

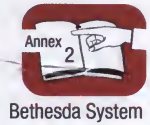


Table 2.1 Cervical precancer: different terminologies used for cytological and histological reporting

Cytological classification (used for screening)		Histological classification (used for diagnosis)	
Pap	Bethesda system	CIN	WHO descriptive classifications
Class I	Normal	Normal	Normal
Class II	ASC-US ASC-H	Atypia	Atypia
Class III	LSIL	CIN 1 including flat condyloma	Koilocytosis
Class III	HSIL	CIN 2	Moderate dysplasia
Class III	HSIL	CIN 3	Severe dysplasia
Class IV	HSIL	CIN 3	Carcinoma in situ
Class V	Invasive carcinoma	Invasive carcinoma	Invasive carcinoma

CIN: cervical intraepithelial neoplasia; LSIL: low-grade squamous intraepithelial lesion; HSIL: high-grade squamous intraepithelial lesion; ASC-US: atypical squamous cells of undetermined significance; ASC-H: atypical squamous cells: cannot exclude a high-grade squamous epithelial lesion.

How often are screening abnormalities found?

The number of precancerous lesions found in a population depends on:

- the frequency of disease in the population;
- the age group screened (for example, if many young women are screened, more LSIL will be found);
- the previous screening status of the women (if women are screened regularly, less HSIL will be found);
- the prevalence of HIV in the screened population (more precancerous lesions are found when HIV prevalence is high).

In a previously unscreened population of women aged between 25 and 65 years, the following percentages of abnormal results are likely:

- LSIL: 3–10%;
- HSIL: 1–5%;
- invasive cancer: 0.2–0.5%.

Natural history of invasive cervical cancer

Invasive cervical cancer is defined by the invasion of abnormal cells into the thick fibrous connective tissue underlying the basement membrane. It starts with a microinvasive stage, which is not visible with the naked eye on speculum examination and has to be diagnosed histologically, using a tissue sample from a cone biopsy or hysterectomy. It then evolves into larger lesions, which may extend to the vagina, pelvic walls, bladder, rectum and distant organs. If left untreated, cervical cancer progresses in a predictable manner and will almost always lead to death. The International Federation of Gynecology and Obstetrics (FIGO) system is often used to describe the extent of cancer invasion and to select treatment options (see Chapter 6).

There are four, usually sequential, routes through which invasive cancer progresses. The disease is generally confined to the pelvis for a long period, where it is accessible to treatment.

1. **Within the cervix.** Spread from a tiny focus of microinvasive cancer, eventually involving the entire cervix which can enlarge to 8 cm or more in diameter. The cancer can be ulcerating, exophytic (growing outwards) or infiltrating (invading inwards).
2. **To adjacent structures.** Direct spread in all directions is possible: downwards to the vagina, upwards into the uterus, sideways into the parametrium (the tissues supporting the uterus in the pelvis) and the ureters, backwards to the rectum, and forwards to the bladder.

3. **Lymphatic.** Spread to pelvic lymph nodes occurs in 15% of cases when the cancer is still confined to the cervix, and increases as the cancer spreads. Lymph node metastases are at first confined to the pelvis and are later found in the chain of nodes along the aorta, eventually reaching the supraclavicular fossa (the space above the collar bone). If the cancer has advanced into the lower third of the vagina, the groin nodes may become involved and will be palpably enlarged.
4. **Distant metastases** through the bloodstream and lymph channels. Cervical cancer cells may spread through the blood stream and lymphatic system to develop distant metastases in the liver, bone, lung and brain.

Cervical cancer and human immunodeficiency virus infection

Immunosuppression, resulting from HIV infection or other causes (e.g. use of antirejection drugs after transplantation), presents particular problems.

HIV-infected women have:

- a higher prevalence of HPV; the risk of infection increases with the degree of immunosuppression;
- a higher prevalence of persistent infection and infection with multiple high-risk HPV types;
- a greater risk of precancer, which increases with the degree of immunosuppression and might be 2–6 times the risk in uninfected women;
- an increased risk of developing cervical cancer;
- diagnosis of invasive disease up to 10 years earlier than the average;
- more frequent presentation with advanced disease with poor prognosis.

It is still unclear if treatment of HIV-positive women with highly active antiretroviral therapy (HAART) substantially affects the natural history of SIL.

ADDITIONAL RESOURCES

- Berek JS et al., eds. *Novak's textbook of gynecology*, 12th ed. Baltimore, MD, Lippincott, Williams & Wilkins, 1996.
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- WHO. *Cervical cancer screening in developing countries*. Report of a WHO Consultation. Geneva, 2002.

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CHAPTER 3: HEALTH PROMOTION: PREVENTION, HEALTH EDUCATION AND COUNSELLING

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Key points

- Health promotion, including education and counselling of women and men, should be an integral part of all cervical cancer control programmes.
- Health education should aim to ensure that women, their families and the community at large understand that cervical cancer is preventable.
- Health education messages about cervical cancer should reflect national policy and should be culturally appropriate and consistent at all levels of the health care system.
- Providers should be trained to discuss sexuality in a non-judgemental way and be able to address behavioural issues related to cervical cancer and HPV.
- Privacy and confidentiality during counselling are essential elements of quality care.

ABOUT THIS CHAPTER

This chapter addresses the importance of integrating health promotion into cervical cancer control activities, through health education, primary prevention and counselling. These three strategies transmit similar messages and require related and overlapping communication skills. The key messages related to behaviour change are outlined, as well as the evidence for the effectiveness of condoms and vaccines in reducing the harm done by HPV. The practice sheets (PS) at the end of the chapter list the key messages to be included in health education about cervical cancer, provide answers to frequently asked questions (FAQs) about cervical cancer and HPV, indicate how to involve men in preventing cervical cancer, and give more information on counselling.

HEALTH PROMOTION

Promoting health at the personal and societal levels, by helping people to understand and reduce their personal risk of illness, avoid harmful behaviours and adopt healthier lifestyles, is a key role of health programmes at all levels. In many countries, prevention has traditionally taken a secondary role to curative care, but is gradually becoming more evident; continuing efforts in this direction are needed. Health promotion can be implemented in multiple ways. Three strategies are particularly useful in relation to cervical cancer: primary prevention (of HPV infection), health education, and counselling.

THE ROLE OF THE PROVIDER

Providing correct information on cervical cancer in the community and in health services is key to raising awareness and reducing illness and deaths. All categories of health care providers, in whatever setting they work, should provide correct and consistent information to women and men on cervical cancer, how it can be prevented, reasons for screening, and the significance and management of any abnormalities detected. The language used should be tailored to the audience and in line with the provider's function and training. Providers should always make sure that the information is fully understood by the woman and her support network. To be able to do this, providers must keep their own knowledge up to date and improve their communication skills.

To change behaviour, knowledge is necessary but is not sufficient. Behaviour change will be more likely if providers assist women to assess their own risk of disease and empower them to reduce this risk. Communication skills are required for educating and counselling women, and for helping those in the target group to understand their need for screening, follow-up and treatment. If cancer is discovered, the women need to be told about the nature and prognosis of their disease. Once clear messages have been developed in simple language, health education in the clinic setting should not take much time, and can be done in group settings as well as in private consultations.

PREVENTION OF HPV INFECTION

HPV is a common virus, which is transmitted by close contact, including penetrative and non-penetrative sexual contact. A large proportion of men and women are infected with HPV at some time in their life. The only certain way to prevent genital HPV infection is to abstain completely from genital skin-to-skin contact and sexual intercourse. However, certain changes in sexual behaviour (e.g. using condoms, delaying first intercourse) offer some protection against HPV.

Using condoms

Condoms only offer partial protection against HPV transmission, because the virus can exist on body surfaces not covered by the condom, such as the perianal area and anus in men and women, the vulva and perineum in women, and the scrotum in men.

Despite this, consistent and correct condom use has been shown to provide important benefits:

- It allows faster HPV clearance in both men and women.
- It increases regression of cervical lesions.
- It reduces the risk of genital warts.
- It reduces the risk of cervical precancer and cancer.

- It protects against other sexually transmitted infections (STIs), including chlamydia and HSV-2 infection, which are possible cofactors for cervical cancer.
- It protects against HIV infection, a known facilitator of both high-risk HPV infection and progression to high-grade lesions.
- It protects against unwanted pregnancy.

Condoms may reduce the risk of developing HPV-related diseases because they decrease the amount of HPV transmitted or because they reduce the likelihood of re-exposure. Whether female condoms (which cover part of the vulva) offer the same or additional HPV protection as male condoms is as yet unknown.



Condoms

Condom promotion and distribution are essential components of all STI control efforts

The future: vaccination against HPV infection

Since most people are exposed to HPV once they become sexually active, an ideal way to prevent HPV infection would be through vaccination prior to exposure. The vaccine should protect against at least the most common high-risk types (HPV 16 and HPV 18), and preferably all the high-risk types. Recently developed candidate HPV vaccines designed to protect against infections with HPV 16 and HPV 18 have given promising results. However, many questions and programme concerns still need to be addressed before any vaccine can be effectively used. For example, it will be important to ensure equitable access to HPV vaccines, in order to attain high coverage of adolescents before they become sexually active.

Any effect of a vaccine on the incidence of cervical cancer would not be detectable for some decades after its introduction. Widespread screening for cervical cancer would therefore need to continue, even after an HPV vaccine programme is fully implemented, in order to detect cervical abnormalities in the unvaccinated and previously infected population, and to monitor and evaluate progress towards the goals of the vaccination programme.

Prevention of possible cofactors

Men, women and adolescents need to be aware of the other factors associated with the development of cervical cancer in women infected with HPV (see Chapter 2). Even though understanding of cofactors remains incomplete, health care providers should develop strategies to reach individuals and communities, to disseminate information and provide advice on changing behaviour, e.g. reducing number of sexual partners,

stopping smoking, delaying first intercourse, and using condoms. Cervical cancer risk is also increased in women who use oral contraceptives for five years or more; however, the increase is very small and the benefits of preventing unwanted pregnancy and unsafe abortion greatly outweigh the risk. There is, therefore, no need to limit the use of hormonal contraceptives.

HEALTH EDUCATION

Health education involves communicating up-to-date general information and messages about changing behaviour in simple, understandable language, to individuals or groups. Messages should use locally and culturally appropriate terms, and should be developed in collaboration with the community and in accordance with national guidelines. It is important that the core of the messages is always the same, regardless of where, by whom and to whom they are given. Health education is not an isolated event; it should be a continuous activity and requires constant effort from managers and providers to maintain their knowledge up to date.



Health education

Health education is needed to ensure optimal programme coverage, which in turn, will lead to increased programme impact. Many barriers to cancer screening programmes can be addressed through education of the community. For example, numerous studies have shown that many women do not attend screening programmes because they are not aware of their risk of cervical cancer or of the benefits of screening in its prevention and early detection. Women in developing countries and rural areas may not have heard of cervical cancer or screening tests, or may not be aware that a positive test result does not necessarily mean that they have cancer or that they are certain to die. Many misconceptions and beliefs about cancer reflect fears about the discovery of a disease they have heard is fatal. Often there is also stigma related to diseases of the reproductive tract, particularly sexually transmitted infections, including HPV. Fear and embarrassment about genital examinations, and concerns about lack of privacy and confidentiality, may keep women from attending services. Such fears and misconceptions can be dealt with by reassuring women about what is involved in an examination and screening. If such information is backed up by skilful, respectful provision of services, women will be more likely to attend and will be more likely to recommend screening to their friends and family.



FAQs

RECOMMENDATION

Health education should be an integral part of comprehensive cervical cancer control.

Some misconceptions and facts about cervical cancer

Misconception	Fact
Intrauterine devices (IUDs) cause cervical cancer.	IUDs are not linked to any increase in cervical cancer.
In screening, part of your body is removed.	Cervical cancer screening involves a gentle collection of cells from the surface of the cervix; no pieces of tissue are removed.
Screening is like a vaccine: once you have had it, you will not get cervical cancer.	Screening in itself does not prevent cervical cancer, but it does detect if the cervix is normal or not. If abnormalities are detected early and are treated, cancer can be prevented.
There is no point in going for cancer screening, because it only tells a woman that she has a fatal condition and nothing can be done for it.	Screening can detect abnormalities before they become cancer. Also, if cancer itself is detected early, it can be cured with proper treatment.
Cervical cancer is seen in women with poor hygiene practices.	There is no evidence that poor hygiene causes cervical cancer.
Use of tampons and herbs can cause cancer of the cervix.	Cervical cancer is caused by a virus infection. Smoking and having multiple sexual partners can increase the risk, but use of tampons and herbs has not been shown to have any effect.

In cervical cancer control programmes, health education includes:

- informing people about cervical cancer, its causes and natural history;
- promoting screening for women in the target group;
- increasing awareness of signs and symptoms of cervical cancer, and encouraging women to seek care if they have them;
- reducing ignorance, fear, embarrassment and stigma related to cervical cancer.



Health education

How to provide health education

- Messages should be developed to address common fears and misconceptions, as well as the stigma attached to STIs.
- Providers should make efforts to overcome their own discomfort in talking about sexual matters and diseases that affect the genital organs.
- Providers should give accurate information in an acceptable and non-judgemental manner.
- Answers to frequently asked questions need to be developed locally, in consultation with the community and in harmony with local beliefs and practices.
- The fact that cervical cancer is linked to HPV, a sexually transmitted infection, raises some difficult questions that providers need to be prepared to answer. Some examples and answers are provided in Practice Sheet 2.



FAQs

Where can health education take place?

Information on cervical cancer can be provided within or outside the health facility, by a variety of health workers: doctors, nurses, health educators, nursing assistants, clinical officers, counsellors and community health workers. Other people, such as community leaders and traditional healers, can also provide health education if they are trained in the key messages formulated by the health authorities.

Health education in health facilities

Information can be provided to groups in waiting areas through posters, health talks, videos and written materials. Messages should be consistent, and should always be designed and pretested with the particular audience in mind. Information and education on cervical cancer for men and women can be integrated into health talks on antenatal and postnatal care, family planning, acquired immunodeficiency syndrome (AIDS), chronic care and STIs. In groups consisting mostly of young women at low risk, messages can be framed simply to inform the group and promote screening for women in the target age. To deliver messages effectively, skills in adult education are needed.

Messages should also be given to individual women during their visits to health facilities, tailored to their age and other risk factors. For example, a woman over 30 years of age, who presents with STI symptoms and who has never been screened should, in addition to receiving education and services specific to her symptoms, be given information on cervical cancer. If she cannot be screened immediately, she should

be strongly encouraged to return soon for screening. On the other hand, a teenager who comes only for family planning can be given general information, assured that she will not need to be screened until she is 25–30 years old, and encouraged to tell older women in her family about the need for screening.

Screening can be offered to all women at risk who attend health facilities for any service for themselves or their children. In addition, everyone who works in a health facility, including cleaners, secretaries, and drivers, can be enlisted in this effort and trained to deliver appropriate messages. For example, cleaners and drivers should know the hours and location of screening services; receptionists can be trained to answer questions on the recommended age for screening and on the nature of the procedure, and to help clients obtain more information.

Outreach in the community

Community education may take place in a variety of settings, such as with religious or community groups, in schools, at sports activities, on health awareness days, or in the context of a screening campaign. Various members of the community can be trained to deliver key messages: medical professionals, teachers, community leaders, health promoters, traditional healers and midwives. Written materials, radio and television messages, newspaper articles, posters and pamphlets are all ways to reach people in the community. The approach to educating the community about cervical cancer and the benefits of screening can be adapted to the audience and the setting, but the content of the messages must not vary.

STORY³

Dawn, a 32-year-old Kenyan woman, was not sick. In fact she was in high spirits. Shortly before, a community health worker's announcement at a funeral had inspired her. He had spoken about a chronic disease that affects women – cancer of the cervix – and explained that the disease is preventable. If cervical cancer is not detected early and treated, a woman can die from the disease.

The **community worker** gave Dawn a card and told her where she should go to have a screening test. "For some reason, I felt it was important for me to attend and find out if I had any risk because, after all, I could get help." When she returned two weeks later, she was told her test was negative meaning it was normal. "I was greatly relieved." Now, she was informed, she only needs to return for another test in three years' time.



Because she was treated so kindly and learned so much, Dawn has begun to speak publicly about her experience whenever an opportunity arises. Many women she has spoken to have followed her advice and have been tested, even if they had no symptoms. Two of these women have reported to Dawn that they were being treated for precancer so they would not get cancer. Dawn is happy to be helping others. "I don't want anyone to die when there is opportunity for us to live longer," she says.

Reaching men

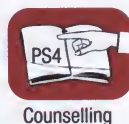
As with other aspects of reproductive health, it is crucial to reach men in clinical and community settings with messages about cervical cancer prevention, sexual transmission of HPV, and the importance of encouraging their partners to be screened and treated when necessary. Unsafe sexual behaviour in men is a risk factor for their partners. Thus, information about prevention of HPV and its role in cervical cancer should be included in STI and HIV prevention messages in all settings where men seek care. Condoms should be widely available.



³ Adapted from: Alliance for Cervical Cancer Prevention. *Women's stories, women's lives: experiences with cervical cancer screening and treatment*. Seattle, WA, 2004.

COUNSELLING

Counselling is face-to-face, personal, confidential communication, in which the counsellor helps the client to make decisions and act on them. Counselling requires listening and conversational skills and knowledge of the subject being discussed. All providers should be trained in counselling skills, to help them communicate effectively with clients.



Counselling can help a person to make decisions only if:

- there is mutual trust between the client and the counsellor;
- there is a two-way transfer of relevant, accurate and complete information.

The content of counselling about cervical cancer will vary according to the client's problem or concern and her individual circumstances. It can cover prevention, screening, follow-up, referral, diagnosis, treatment of precancerous conditions, and treatment of invasive cancer. Counselling can also help patients and their families to cope with a diagnosis of invasive cancer and terminal disease. Such counselling may involve only the patient, or also her partner and other family members, especially if decisions concerning severe disease or costly treatment need to be made. A good counsellor uses verbal and non-verbal communication skills, and helps the client feel at ease by empathizing with her situation, reassuring her, and fostering a sense of partnership in helping her solve her problem. Providers at all levels involved in cervical cancer control who have face-to-face contact with patients may provide counselling. The depth and detail of communication will vary according to the patient's situation and needs and the category and level of provider. Counselling should be structured to educate the woman, review the results of screening and follow-up, present alternative services and procedures, and discuss any follow-up she may need. This will give the woman the tools she needs to make rational decisions for herself.

Who needs to be counselled?

All women who have to decide whether to have a service should receive counselling, as well as those who have chosen to have the service and need information on what it entails and how it relates to their present and future health. Some guidelines on good counselling are found in Practice Sheet 4.

Privacy and confidentiality

Ensure *privacy* by conducting counselling in a setting where the woman and the provider will not be seen or heard, except by people specifically agreed to by the woman. *Confidentiality* is also essential, which means that nothing that is discussed during a consultation or found during an examination may be disclosed to anyone, without prior authorization.

Privacy and confidentiality are essential in counselling, as in all aspects of patient care, and are especially important in relation to conditions that involve the genital area and that may require an examination that is embarrassing to the patient. If a patient feels that there is lack of privacy in a clinic or that the provider is judgemental or disapproving, or might reveal information to others, she may choose to withhold important information, attend a distant clinic or not seek care at all.

- Ensure that no one can see or overhear consultations, counselling and examinations.
- Ensure confidentiality: special efforts are needed in many health care settings, particularly those that are busy or crowded.
- Store forms and records securely; only relevant staff should have access to them.
- Avoid talking about patients with other clinic staff, both inside and outside the clinic.
- Treat patients with respect, regardless of their age, illness, lifestyle and marital or socioeconomic status.
- Health care providers who know the extended families or neighbours of patients must take extra care to reassure patients that confidentiality will be respected.

HEALTH EDUCATION AND COUNSELLING AT DIFFERENT LEVELS

In the community



- Assess gaps in knowledge, myths and negative attitudes prevalent in the community.
- Develop key messages about prevention and use them in health education and counselling.
- Give health talks tailored to specific audiences (young people, men, women of different ages) in different venues.
- Distribute information, education and communication (IEC) materials.
- Counsel individual women in the community about cervical cancer and its prevention, screening, and treatment (depending on individual needs).

At the health centre



- Use every opportunity to provide information and education, and to promote behaviour change to groups of patients.
- Counsel individual women and men, as well as couples, on cervical cancer prevention and early detection.
- Promote screening for women in the target age group, in waiting rooms and outpatient clinics and by outreach to the community.
- Train and assist community health workers and community volunteers to educate the community. Ensure that they use agreed key messages.

At the district hospital



- Educate and counsel women in waiting rooms, outpatient clinics and wards on cervical cancer, its prevention and early detection.
- Promote screening at all opportunities, including in outreach activities to the community.
- Train and supervise workers, and support education in communities and health centres, ensuring that messages on cervical cancer prevention are consistent.

At the central hospital



Carry out all activities performed at district hospitals, plus:

- Develop clear information and education materials for patients and families on cervical cancer diagnosis, treatment and palliative care.
- Inform and educate policy-makers and decision-makers on cervical cancer, its effects on health in the population, and the costs to the system, as well as the cost-benefit of organized efforts to prevent and detect it.

Counselling messages

The community health workers and other health care providers can talk to individual women who consult them about:

- the target group for cervical cancer screening;
- the screening test that is used, how it is done and what it can tell about the cervix;
- what is involved in a pelvic examination and screening test, and where and when screening is available.

They can also:

- help overcome women's reluctance to have a pelvic examination;
- stress the need to follow advice regarding return to the health centre for results or follow-up;
- explain that she will be given a thorough explanation of the clinic procedures and she can accept or decline to have any of them (informed consent);
- tell her that she may bring someone with her if she wishes.

ADDITIONAL RESOURCES

- ACCP. *Planning and implementing cervical cancer prevention and control programs: a manual for managers*. Seattle, WA, Alliance for Cervical Cancer Prevention, 2004.
- Bradley J et al. *Whole-site training: a new approach to the organization of training*. New York, Association for Voluntary Surgical Contraception, 1998 (AVSC Working Paper, No. 11; www.engenderhealth.org).
- Burns A et al. *Where women have no doctor: a health guide for women*. Berkeley, CA, Hesperian Foundation, 1997.
- *Cervical cancer prevention guidelines for low-resource settings*. Baltimore, MD, JHPIEGO Corporation, 2001.
- *GATHER guide to counselling*. Baltimore, MD, Johns Hopkins School of Public Health, Population Information Program, 1998 (Population Reports, Series J, No. 48; www.jhuccp.org).
- Hubley J. *Communicating health: an action guide to health education and health promotion*. London, Macmillan, 1993.

- *Prevention and management of reproductive tract infections (RTIs): the comprehensive reproductive health and family planning training curriculum.* Watertown, MA, Pathfinder International, 2000.
- WHO. *Sexually transmitted and other reproductive tract infections. A guide to essential practice.* Geneva, 2005.
- *Working with men.* New York, EngenderHealth, 2005 (<http://www.engenderhealth.org/ia/www/index.html>) [resources for male involvement in reproductive health programmes].

PRACTICE SHEET 1: HEALTH EDUCATION

PS 1

This Practice Sheet provides key evidence-based messages that can lead to behaviour changes that will reduce the harm done by cervical cancer.

To be an effective health educator about cervical cancer:

- You should have correct up-to-date knowledge about cervical cancer and good communication skills.
- You should transmit consistent messages about cervical cancer, tailored to the educational background and culture of the audience.
- You should be comfortable talking about sexuality and behaviour that increases risk of HPV infection and cervical cancer.
- You should feel comfortable explaining how to use male and female condoms.
- Your messages must be in line with national policy and appropriate to the local situation.

Key cervical cancer messages for men and women

- Cervical cancer is the leading cause of cancer deaths in women in their 40s, 50s and 60s in developing countries.
- Cervical cancer is caused by an infection with human papillomavirus, a very common viral, sexually transmitted infection. This infection very often occurs in young men and women who may not be aware of it.
- Condom use offers partial protection from HPV and may lower the risk of developing HPV-related diseases, such as genital warts and cervical cancer.
- Most HPV infections do not persist and do not cause cancer.
- The few HPV infections that do persist may lead to precancer; if not treated, this may become cancer.
- It usually takes many years for HPV infection to cause precancer and years longer for precancer to progress to cancer.
- Screening can detect precancer. Most abnormal conditions found on screening are curable.
- Women aged 25 years and older are more likely than younger women to have cervical precancer. Women should be screened at least once between the ages of 35 and 45 years and, if possible, every 3 years from age 25 to 65 years (or according to national guidelines).
- Screening is relatively simple, quick and painless.
- Precancerous lesions can be treated simply, and a hospital stay is not usually required.

PS 1

- If cancer is found and treated early, it can be cured.
- Women need to seek medical care promptly if they have abnormal discharge, vaginal bleeding, bleeding after sexual intercourse, or any bleeding after menopause; these may be signs of cervical cancer.
- Women have a right to make their own decisions about their health (involving their partner or family if they so wish). While screening and follow-up are highly recommended, women should be free to refuse any test or treatment.

Messages about personal behaviour

- Delay first sexual intercourse: people who engage in early sexual activity are more likely to be infected with HPV. Younger women are more vulnerable to being infected with a single sexual act.
- Delay first childbearing: the hormones of pregnancy may increase the risk of developing cervical cancer.
- Limit the number of pregnancies: women who have had 5 or more children have a higher chance of developing cervical cancer.
- Reduce the number of sexual partners: the more partners a person has, the greater the chance of becoming infected with an STI, including HPV and HIV, both of which increase the risk of cervical cancer.
- Avoid partners who have multiple partners: women whose partners have or have had multiple partners have a higher rate of cervical cancer.
- Use condoms: condoms have been shown to protect against STI and to reduce the risk of cervical cancer.
- Do not smoke tobacco: women who smoke have a higher risk of almost all cancers, including cervical cancer.
- Seek treatment immediately if you have symptoms of an STI, or suspect that you have been exposed to an STI. Some STIs may facilitate the development of cervical cancer and cause other undesirable health effects, including infertility. Prompt treatment of STIs may protect against HPV and cervical cancer.
- If you are over 25, go for screening. Almost all women who have had sexual intercourse have probably been exposed to HPV. Screening can detect early lesions so they can be treated before they have a chance to progress to cancer.
- Special message to men and boys: reduce the number of your sexual partners, and always use condoms, especially with new partners.

Note to the educator

Some of the above behaviours may be difficult to put into practice, especially for women who cannot control when, with whom, and how they have sexual intercourse. Making men aware of these facts may lead them to treat their partners more equitably.

Supplies for health education

Health education is best provided in face-to-face encounters. Using the following materials, if they are appropriate to your community, can assist:

- flipcharts;
- brochures;
- slide shows;
- drama and role-plays;
- videos;
- radio and television programmes;
- presentations by experts who can communicate in nontechnical language.

PS1

Practice Sheet 1: Health Education

PRACTICE SHEET 2: FREQUENTLY ASKED QUESTIONS (FAQs) ABOUT CERVICAL CANCER

PS 2

Men, women and even health care providers often lack information on cervical cancer. This Practice Sheet lists some frequently asked questions and provides answers to them. You and your colleagues should add other questions relevant to the local situation, and their answers.

CAUSES AND RISK FACTORS

Q What is cancer?

A Cancer is the uncontrolled growth of certain cells in the body, causing tumours or growths. Not all growths are cancer. Those that spread to other parts of the body and can interfere with normal functions are called cancer.

Q What is cervical cancer?

A It is cancer that begins on the cervix, which is the opening of the womb. Cells on the cervix begin to grow abnormally and sometimes, if they are not treated, they become cancer. However, these early (precancerous) changes can disappear on their own, without causing problems.

Q What causes cervical cancer?

A Cervical cancer is caused by infection with a virus called human papillomavirus or HPV. Most of the time, HPV infection disappears without treatment; sometimes, however, HPV stays in the cells for years and, in some women, eventually causes cervical cancer. Not much is known about why some women get cervical cancer and others do not.

Q Is cervical cancer a sexually transmitted infection (STI)?

A No, but HPV is a sexually transmitted infection, which is quite common in both men and women. Only a few women with HPV will go on to get precancer. If not treated, some of these women will develop cervical cancer, many years after they were infected with HPV.

PS 2

Q Can cervical cancer be prevented?

- A** Yes. Limiting the number of new sexual partners, using condoms, delaying first sexual relations and childbearing, and not smoking tobacco help prevent cervical cancer. HPV vaccines are now being tested and will probably be the most effective means of prevention, when they become widely available. Once they are available, they will need to be given to young people before they start to have sexual relations.

The best way to prevent cervical cancer today is through screening of women for preinvasive cancer, which can be treated before it becomes cancer.

Q Who is at risk of cervical cancer?

- A** All women who have had sexual intercourse are potentially at risk because they might have been infected with HPV. Cervical cancer is most commonly found in women in their 40s and 50s. The women most at risk are those who have never been screened, had sexual intercourse and children at a young age, have had more than 5 children, have multiple partners or partners who have multiple partners, and smoke tobacco. Being infected with HIV also puts women at higher risk.

Q Are women who take hormonal contraceptives at increased risk for cervical cancer?

- A** There is a slightly increased risk when oral contraceptives are used for a long time. Women who take OC, as others, should be screened regularly. There is no reason to stop using contraceptives as the benefits outweigh the risks.

Q Do genital warts cause cervical cancer?

- A** No. Cancer is caused by certain high-risk types of HPV. Genital warts are caused by different low-risk HPV types, which do not cause cancer.

SCREENING**Q What is a screening test?**

- A** A screening test is a test done on people who are healthy and without symptoms, to identify those with a higher chance of getting a particular disease. A cervical cancer screening test can determine if a cervix is normal or not. It can detect early signs of disease before a woman has symptoms, when treatment can prevent the disease from developing.

Q Who should be screened for cervical cancer?

- A** Women between the ages of 25 and 65 years (or according to national norms) should have a screening test to detect early changes. Women younger than 25 almost never get cervical cancer and do not need to be screened. Women who have never had sexual intercourse do not need to be screened.

Q What exactly is done during screening?

- A** The most common screening test is the Papanicolaou (Pap) smear. The health care provider will do a genital examination to look at the cervix, collect a sample of cells from your cervix, and send it to the laboratory to be examined. Other tests are sometimes used to screen for cervical cancer, such as looking at the cervix after putting vinegar on it. The provider will tell you about the test used in your area.

Q What if my test is negative?

- A** If your screening test is negative, it means that you do not have any changes that might develop into cervical cancer. It is important to be screened at regular intervals (every 3–5 years, depending on local norms) to make sure that such changes do not develop.

Q What if my test is positive?

- A** In most cases a positive test means you have precancer, a condition that might go away on its own or that can be easily treated in an outpatient setting. You might need to have other tests to make sure that what you have is precancer, and not cancer. Sometimes a positive test means you have cancer. In this case, you will be referred to a hospital for treatment.

PRECANCER AND CANCER**Q What is precancer?**

- A** Precancer results when the cervix has been infected with high-risk HPV for some time. It is easily treated. Most precancer goes away on its own, but if it persists and is not treated, it can become cancer.

Q What are the signs of cervical cancer?

- A** Early cervical cancer usually has no signs, which is why screening is so important. Signs of cancer are: vaginal spotting or bleeding after sexual intercourse, between menstruations, or after menopause, and foul-smelling discharge that does not go away even with treatment. If you have any of these signs, you should see a health care provider, because the earlier cancer is found, the better your chance of being cured.

PS 2

Q Can cervical cancer be treated?

- A** Most cervical cancer can be successfully treated if it is found early. In middle-aged women who have never been screened, cancer may be discovered late, when it has already spread beyond the cervix and is more difficult to treat.

Q Can cervical cancer be cured?

- A** Yes, cervical cancer is curable, if it is found before it has spread too far. The earlier cancer is found, the better your chance of being cured.

Q How is cervical cancer cured?

- A** There are two major ways to treat and cure cervical cancer—by an operation to remove it surgically, or by radiation therapy which kills the cancer cells. Sometimes both methods are used.

PRACTICE SHEET 3: HOW TO INVOLVE MEN IN PREVENTING CERVICAL CANCER

PS 3

Cervical cancer is exclusively a woman's disease, but men can play a key role in preventing and treating it. Infection with HPV is sexually transmitted, and men therefore can contribute to preventing it. This Practice Sheet provides basic information that men need, and suggests ways to involve them in cervical cancer control.

BASIC INFORMATION FOR MEN ON CERVICAL CANCER

- General messages can be found in Practice Sheet 1 on health education.
- Cervical cancer is common and is usually seen in women aged 40 years or over. Cervical cancer develops from precancer, which can be detected by screening and treated. Women over 25 years should be screened.
- Most cervical cancer is caused by infection with a virus, the human papillomavirus (HPV). This virus is easily passed between people who have sexual contact. It causes no symptoms.
- HPV can also threaten men's health; if it persists, it can increase the risk of cancer of the penis.
- HPV is sexually transmitted, but penetration is not essential as the virus can live on the skin, outside the genital area.
- Using condoms does not offer complete protection, but it can cause infections to disappear faster, and thus has a role in the prevention of cervical cancer.
- Smoking tobacco can increase the risk of many cancers in men and women, including cervical cancer in women infected with HPV.
- Men can play a key role in the prevention of cervical cancer in women, by:
 - reducing the number of their sexual partners and using condoms if they have more than one relationship;
 - using condoms to prevent STIs, including HIV/AIDS;
 - encouraging their partners to be screened if they are over 25 years of age;
 - collaborating with partners to avoid unwanted pregnancies and pregnancy at very young age;
 - not smoking and helping their partners not to smoke.
- Men whose partner is found to have precancer or cancer can support and assist her in obtaining the recommended treatment, by accompanying her to clinical appointments, and by learning about cervical cancer.



Health education

PS3

- Men need to cooperate with their partners, if they are told in the clinic to abstain from sexual intercourse, as may be the case following certain tests and treatments.
- Men can reduce the work burden of their partner when she has had surgery, chemotherapy, or radiation for cervical cancer. These treatments can help cure the cancer, but they can make the woman feel tired and weak. She will need time for rest and recuperation.
- Where a woman has very advanced cervical cancer, her partner can assist by providing maximum comfort.
- Men can also contribute to reducing cervical cancer deaths in their community and country, by advocating for women's health programmes.

To men:

You have a very important role in the prevention and treatment of cervical cancer. Please use condoms consistently and correctly; this will lead to improved sexual and reproductive health for yourself and your partner.

PRACTICE SHEET 4: COUNSELLING

PS 4

What is counselling?

Counselling is face-to-face, personal and confidential communication, aimed at helping a person (and her family) to make informed decisions and then to act on them. It is a two-way exchange of relevant and accurate information. To be an effective counsellor, you should have the ability to listen, up-to-date knowledge, and conversational skills.

What background knowledge on cervical cancer does the patient need to have?

The counsellor should ensure that all women, especially those targeted for cervical cancer control programmes, have the following basic knowledge:

- the basic anatomy of the cervix, its location in the pelvis, the changes it undergoes at different ages, and how it can be examined;
- what cervical cancer is, what causes it, and the risk factors for developing it;
- how to prevent cervical cancer, with emphasis on screening and treatment of precancerous lesions;
- what screening test and which treatments for abnormalities detected on screening are used locally;
- options available for women who have invasive cancer detected by screening and diagnosis.



Health education

Drawings and illustrations, as well as the information provided in this Guide and in Practice Sheets 1 and 2, are useful aids in explaining the above.



FAQs

What must the counsellor ensure?

- Privacy: no one, unless specifically permitted by the woman, should be able to see or hear anything that goes on between the woman and the counsellor.
- Confidentiality: nothing seen, heard or done during counselling and examination should be known by anybody else, unless the woman specifically authorizes it.
- Mutual trust between provider and patient.
- Sensitivity in addressing and discussing private topics, particularly related to sexuality and behaviour.

Suggestions for counselling on cervical cancer

1. Welcome the woman warmly by name and introduce yourself.
2. Sit close enough that you can talk comfortably and privately.
3. Make eye contact; look at her as she speaks.
4. Assure her that nothing that is discussed will be repeated to anybody.
5. Use language that she can understand and provide relevant information.
6. Tailor the information you give and the discussion to the reason she is here today.
7. Listen attentively and take note of her body language (posture, facial expression, eye contact).
8. Try to understand her feelings and point of view.
9. Use open-ended questions to invite more than “yes” or “no” answers.
10. Be encouraging. Nod or say: “Tell me more about that.”
11. Try to identify her real concerns.
12. Explain all the options available and respect her choices.
13. Always verify that she has understood what was discussed by having her repeat the most important messages or instructions.
14. Invite her to return if and when she wishes.

Counselling “do’s”

- Ensure privacy.
- Greet the woman by name and introduce yourself.
- Look the woman in the face unless culturally not appropriate.
- Use a natural, understanding manner.
- Be empathetic: place yourself in the woman’s situation.
- Use approving body language (nod, smile, etc., as appropriate).
- Use simple language and terms the woman understands.
- Answer her questions truthfully.
- Allow enough time for the session.
- If she has doubts, invite her to return later to inform you of what she (and possibly her family) has decided.

Counselling “don’ts”

- Appear to be distracted (looking at your watch, answering the phone).
- Use a harsh tone of voice, or act impatient.
- Allow interruptions during the visit.
- Interrupt the woman.
- Be critical, judgemental or rude.
- Overwhelm the woman with too much detail or irrelevant information.
- Use medical words the woman does not understand.
- Force a decision; if she has doubts, invite her to return later to inform you of what she (and possibly her family) has decided.

STANDARD COUNSELLING STEPS FOR ANY WOMAN HAVING A TEST, PROCEDURE OR TREATMENT

Before the procedure



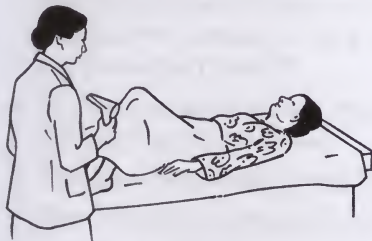
- Explain again why it is important for her to be screened or to undergo the procedure or the treatment recommended.

- Explain what will be done: how it is done, what it can show, possible need for future tests or treatments.



Informed consent

While you are doing the procedure



- Invite and respond to informed consent, including consent to be contacted at home or work if necessary.

- Tell the woman what you are doing at each step. If what you are about to do may cause pain, cramps or other discomfort, warn her in advance. This will help her feel comfortable.

After the procedure



- Explain what you did.
- Describe any noted abnormalities or reassure the woman that you did not see anything unusual.
- Agree a date for the return visit.
- Explain the importance of her returning to the clinic as planned.

PS4

If you noted something for which you wish to refer her to a higher level for further examination or tests:

- Explain why, where and when she must go, and whom to see.
- Stress the importance of keeping this appointment.
- Answer any questions she has or, if you do not know the answer, find someone who does.
- Invite her to return if she has any questions or concerns about this appointment, and respond or find answers from someone who knows.

PRACTICE SHEET 5: HOW TO USE MALE AND FEMALE CONDOMS ⁴

PS 5

Messages about condoms to be communicated to men and women

- Condoms are the most reliable available method of protection against STIs.
- Used correctly, a condom forms a barrier that keeps out even the smallest bacteria and viruses.
- Because HPV can infect tissue outside of the area normally covered by a condom, condoms cannot completely prevent HPV infection.
- However, the use of condoms has been shown to:
 - speed up HPV clearance;
 - reduce the risk of genital warts;
 - reduce the risk of cervical cancer;
 - protect against Chlamydia and HSV infection (possible cofactors for cervical cancer);
 - protect against other STIs;
 - protect against HIV infection;
 - protect against pregnancy.

When should you recommend that a woman use condoms?

- If she is diagnosed with an HPV infection or a low-grade lesion (LSIL) which is being watched.
- When there is a risk of infection or bleeding and she is not able to follow advice to abstain from intercourse. This is the case after certain procedures, such as cryotherapy (see Chapter 5).
- For simultaneous prevention of most sexually transmitted infections, including HIV, and pregnancy (dual protection).
- While she is being treated for any STI.
- When her partner has symptoms or is being treated for an STI.

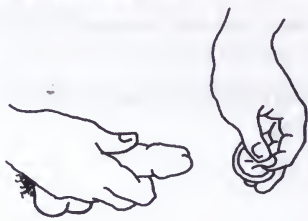
Condoms only protect when they are used consistently and correctly!

⁴ Adapted from: *Sexually transmitted and other reproductive tract infections. A guide for essential practice*. Geneva, WHO, 2005.

MALE CONDOMS

Male condoms are made of latex; they are widely available and inexpensive, highly effective in preventing STIs and partially effective in preventing HPV transmission.

Instructions for use



1. Remove the condom from the package carefully, to avoid tearing.



2. Squeeze the air out of the tip of the condom.



3. Unroll the condom onto the erect penis.



4. After ejaculation, withdraw the penis from the vagina while the penis is still erect. Hold on to the rim of the condom while withdrawing to prevent it from slipping off and the semen spilling into the vagina.



5. Remove the condom from the penis, and tie a knot in it to prevent spills or leaks. Dispose of the condom safely (where it cannot cause any hazard).

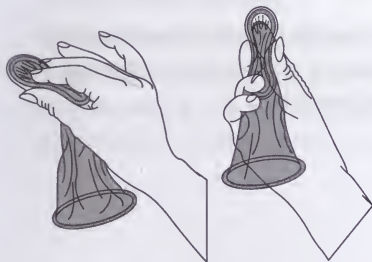
FEMALE CONDOMS

The female condom is a soft, loose-fitting sheath with a flexible polyurethane ring at each end. The inner ring at the closed end is inserted into the vagina. The outer ring at the open end remains outside the vagina during intercourse and covers outer genitalia. Female condoms are made of polyurethane and come in only one size. They probably offer the same level of protection as male condoms, but are considerably more expensive. One advantage is that the woman has greater control in using them than in using male condoms.

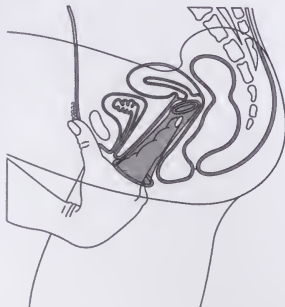
Instructions for use



1. Remove the female condom from the package, and rub it between two fingers to be sure the lubricant is evenly spread inside the sheath. If you need more lubrication, squeeze two drops of the extra lubricant included in the package into the condom sheath.



2. The closed end of the female condom will go inside your vagina. Squeeze the inner ring (closed end) between your thumb and middle finger. Insert the ring into your vagina.



3. Using your index finger, push the sheath all the way into your vagina as far as it will go. It is in the right place when you cannot feel it.

Do not worry, it cannot go too far.

PS5



4. The ring at the open end of the female condom should stay outside your vagina and rest against your labia (the outer lip of the vagina). Be sure the condom is not twisted. Once you begin to engage in intercourse, you may have to guide the penis into the female condom. If you do not, be aware that the penis could enter the vagina outside of the condom's sheath. If this happens, you will not be protected.



5. After intercourse you can safely remove the female condom at any time. If you are lying down, remove the condom before you stand to avoid spillage.

Dispose of the female condom safely (where it cannot cause any hazard). Do not reuse it.

INSTRUCTIONS FOR COUNSELLING ON CONDOM USE

- Male and female condoms are only effective if they are used correctly every time when having intercourse.
- Providers need to overcome their own reluctance to talk about and touch condoms. They should show patients and their partners how a condom is used.
- When instructing and counselling patients and their partners in how to use condoms, use a model penis or vagina. These can be bought, or you could make one with locally available materials.
- Demonstrate how to open a condom package, how to unroll the condom, how to place it on the erect penis (for a male condom) or inside the vagina (for a female condom), how to remove the penis from the vagina when still erect, how to remove the condom, and how to dispose of it safely.
- During or after your demonstration, ask the patient and her partner to do the same actions using a new condom on the same or another model. Gently correct any errors.
- Advise patients and partners to be particularly careful about the following:
 - When opening a condom package, avoid tearing the condom; do not use teeth or long nails.
 - Use condoms only once.
 - Have a supply always available.
- Provide sufficient condoms to every patient, including those who have been advised to abstain from sexual intercourse. Make sure women and men know how to use them, and where to obtain them in the community.

PS5

Practice Sheet 5: How to Use Male and Female Condoms

4

CHAPTER 4: SCREENING FOR CERVICAL CANCER

CHAPTER 4: SCREENING FOR CERVICAL CANCER

Key points

- Screening is testing of all women at risk of cervical cancer, most of whom will be without symptoms.
- Screening aims to detect precancerous changes, which, if not treated, may lead to cancer.
- Screening is only effective if there is a well organized system for follow-up and treatment.
- Women who are found to have abnormalities on screening need follow-up, diagnosis and possibly treatment, in order to prevent the development of cancer or to treat cancer at an early stage.
- Several tests can be used in screening for cervical cancer. The Pap smear (cytology) is the only test that has been used in large populations and that has been shown to reduce cervical cancer incidence and mortality. Other tests (VIA, VILI, HPV) show promise but there is as yet no comparable evidence on their effectiveness. Large studies are still under way.
- Regardless of the test used, the key to an effective programme is to reach the largest proportion of women at risk with quality screening and treatment.
- Organized screening programmes designed and managed at the central level to reach most women at risk are preferable to opportunistic screening.

ABOUT THIS CHAPTER

This chapter provides detailed information on screening, and explains why organized screening is superior to opportunistic screening. It describes available screening tests and their comparative advantages and disadvantages.

ROLE OF THE HEALTH CARE PROVIDER

The health care provider is a central figure in any coordinated public health effort to screen women for cervical cancer. Such an effort may include the ministry of health, programme planners, managers, laboratory technicians, health professionals and community workers.

The role of health care providers is to ensure that:

- Women who come for screening receive appropriate information and counselling.
- National guidelines on cervical cancer screening and treatment are followed.
- Screening is well organized and no opportunity to screen targeted women attending services is missed.

- Each woman who comes for screening understands what is involved and gives informed consent for screening and follow-up.
- The screening test, treatment and referral are performed competently; patients are properly assessed and infection control measures are strictly adhered to.
- Women screened are informed of their test results, especially if they are inadequate or positive (abnormal).
- Any sexual and reproductive health problems identified by either the patient or the provider are managed appropriately.
- Appropriate and confidential records are kept in the facility; the records may be given to the woman herself.
- Women who need repeat screening, further testing, referral, or care after treatment are followed up appropriately.

These responsibilities are further explained in this chapter.

STORY⁵

Pratibha is a 37-year-old woman living in Maharashtra, India. One day, when she returned home from fetching water, she found two women health workers talking with her husband. The health workers asked her many questions, such as how old she was, when she married, and how many children she had. Then they told her about cervical cancer and about an opportunity for her to be screened in the village. Pratibha asked why she was selected for this and she was relieved to learn that all women over 30 years old in the village were being visited and invited to attend the screening clinic. One of the advantages of attending this programme was that testing and treatment (if needed) were free. Almost all the women invited attended the clinic, including Pratibha. The test was fast and painless, as she had been told it would be. After the examination, the health worker emphasized that she should return in two weeks to get the test results. When Pratibha returned, she was told that her test was normal and that it would be important for her to repeat the test every 3 years.



⁵ Adapted from: Alliance for Cervical Cancer Prevention. *Women's stories, women's lives: experiences with cervical cancer screening and treatment*. Seattle, WA, ACCP, 2004.

SCREENING PROGRAMMES

What is screening?

Screening is a public health intervention used on a population at risk, or target population. Screening is not undertaken to diagnose a disease, but to identify individuals with a high probability of having or of developing a disease. Women targeted for screening for cervical cancer may actually feel perfectly healthy and may see no reason to visit a health facility.

Not all diseases can be screened for. The following criteria should be met by any disease that is the object of a screening programme:

- The disease must have serious public health consequences.
- The disease must have a detectable preclinical stage (without symptoms).
- The screening test must be simple, non-invasive, sensitive, specific, inexpensive and acceptable to the target audience.
- Treatment at the preclinical stage must favourably influence the long-term course and prognosis of the disease.
- Any further testing and treatment needed must be available, accessible and affordable for those who have a positive screening test.

Cervical cancer meets these criteria.

Screening programmes will only be successful if the following elements are present:

- high coverage ⁶ (80%) of the population at risk of the disease;
- appropriate follow-up and management for those who are positive on screening. Efforts to increase coverage will be wasted if those who test positive are not followed up correctly;
- effective links between programme components (e.g. from screening to diagnosis and treatment);
- high quality of coverage, screening tests, diagnosis, treatment, and follow-up;
- adequate resources.

Cervical cancer screening aims to test the largest possible proportion of women at risk and to ensure appropriate follow-up for those who have a positive or abnormal test result. Such women will need diagnostic testing and follow-up or treatment. Colposcopy and biopsy are often used to reach a specific diagnosis of the extent of the abnormality in women with a positive screening test (see Chapter 5).

⁶ "Coverage" is the proportion of women in the target age group who are screened at the recommended intervals during a given time period. The number of screening tests done is not coverage, since this number may include women outside the target age, and women screened more often than recommended.

Organized and opportunistic cervical cancer screening

Organized screening

Organized screening is designed to reach the highest possible number of women at greatest risk of cervical cancer with existing resources. It is usually planned at the national or regional level. An organized screening programme should specify:

- the target population;
- screening intervals;
- coverage goals;
- a mechanism for inviting women to attend screening services;
- the screening test or tests to be used;
- the strategies to ensure that all women found positive on screening are informed of their result;
- a mechanism for referring women for diagnosis and treatment;
- treatment recommendations;
- indicators for monitoring and evaluating the screening programme.

Opportunistic screening

Opportunistic screening is screening done independently of an organized or population-based programme, on women who are visiting health services for other reasons. Screening may be recommended by a provider during a consultation, or requested by a woman. Opportunistic screening tends to reach younger women at lower risk, who are attending antenatal, child health and family planning services.

It is generally accepted that organized screening is more cost-effective than opportunistic screening, making better use of available resources and ensuring that the greatest number of women will benefit. However, both organized and opportunistic screening can fail because of poor quality-control, low coverage of the population at risk, overscreening of low-risk populations, and high loss to follow-up.

Benefits and risks of screening

The benefits and risks of screening should be discussed with women as part of general health education and before obtaining informed consent. The benefits of screening have been described in previous chapters. However, as with all large efforts directed towards healthy populations, screening for cervical cancer has the potential to produce undesirable outcomes, such as:

- psychological consequences – anxiety and fear about being tested for cancer;
- a mistaken belief that a positive test is a cancer diagnosis;

- false positive test results (abnormalities reported in women whose cervix is normal), which may lead to unnecessary interventions and anxiety;
- false negative test results (a normal screening test in women with cervical abnormalities);
- identification of other illnesses, for which treatment may not be available.

Following the recommendations in this Guide will, in general, help to minimize these undesirable outcomes.

Target groups and frequency of screening

Decisions on the target age group and frequency of screening are usually made at the national level, on the basis of local prevalence and incidence of cervical cancer, related factors such as HIV prevalence, and availability of resources and infrastructure.

All existing data on recommended ages and frequency of screening are derived from experience in cytology programmes. To date, there are no comparable data from programmes using HPV-based and visual screening methods.

When deciding on target age group and screening frequency, planners should take into account the following:

- HPV infection is very common in young women, but most infections are transient.
- Only a small percentage of all HPV infections will lead to invasive cancer.
- Cervical cancer usually develops slowly, taking 10–20 years from early precancer to invasive cancer.
- Cervical cancer is rare before the age of 30 years. Screening younger women will detect many lesions that will never develop into cancer, will lead to considerable overtreatment, and is not cost-effective.
- Screening every three years is nearly as effective as yearly screening. If resources are limited, screening every 5–10 years – or even just once between the ages of 35 and 45 years – will significantly reduce deaths from cervical cancer.

RECOMMENDED TARGET AGES AND FREQUENCY OF CERVICAL CANCER SCREENING

- New programmes should start by screening women aged 30 years or more, and include younger women only when the higher-risk group has been covered. Existing organized programmes should not include women less than 25 years of age in their target populations.
- If a woman can be screened only once in her lifetime, the best age is between 35 and 45 years.
- For women over 50 years, a five-year screening interval is appropriate.
- In the age group 25–49 years, a three-year interval can be considered if resources are available.
- Annual screening is not recommended at any age.
- Screening is not necessary for women over 65 years, provided the last two previous smears were negative.

Special considerations

Before embarking on a widespread screening programme, national planners should ensure that the services needed to manage newly identified cancer cases are in place. To treat invasive cancer effectively, specialized facilities are needed; these must be in place before a screening programme is put into effect (see Chapter 6).

If a population has not previously been screened, many cases of pre-existing cancer in different stages will be detected in a new screening programme. Women whose disease is very advanced, or for whom treatment is impossible for any reason, should receive palliative care (see Chapter 7).

Screening in settings with high HIV prevalence

In settings with high HIV prevalence, screening for cervical cancer is particularly important. HIV-positive women have more persistent HPV infections, and a higher incidence of cervical precancer and, in some settings, invasive cervical cancer. Where HIV is endemic, screening results may be positive in up to 15–20% of the target population. Cytology screening is equally effective in HIV-positive and HIV-negative women. Although HIV-infected women are at greater risk of precancer and cancer, screening, follow-up and treatment may not be a priority for the women themselves, who have competing health or social needs. All women, regardless of their HIV status,

should be encouraged to be screened for cervical cancer, provided that they have access to affordable services. Care should be taken not to link a positive cervical cancer screening test to HIV testing. However, a woman with precancer may benefit from knowing her HIV status, especially if antiretroviral treatment (ART) is available. Screening criteria for women with known HIV infection should be developed at the national level with these issues in mind.

RECOMMENDATION

Women should be offered the same cervical cancer screening options irrespective of their HIV status.

Screening of pregnant women

Not screening for cervical cancer during pregnancy is sometimes seen as a missed opportunity. Visits for antenatal care may be a good occasion for screening. However, integrating screening into routine antenatal care is not the best option for the following reasons:

- Most pregnant women are younger than the target group.
- In some cultures, pregnant women may be reluctant to undergo a gynaecological examination.
- During pregnancy, interpretation of screening tests, such as cytological tests, is more difficult.
- Regression of CIN during pregnancy is minimal, but there is a significant rate of spontaneous regression postpartum.
- A biopsy for diagnosis should be taken from a pregnant woman only if invasive cancer cannot be ruled out.
- Treatment of preinvasive disease is contraindicated during pregnancy.

Women in the target age group who attend antenatal services should be advised to return for screening 12 weeks after giving birth. However, if a cervical abnormality is noted on speculum examination, or if the provider feels there is a risk that the woman will not return, she should be offered screening during the visit. In addition, the provider can suggest that the woman should encourage other women in the target age group in her extended family to be screened.

Screening family planning clients

Opportunistic cervical cancer screening is often integrated into family planning services. Family planning counselling provides a good opportunity to discuss the benefits of cervical cancer screening and a gynaecological examination is often more easily accepted during a reproductive health consultation. Screening should be encouraged and performed on clients of family planning services within the target age group. Contraceptive users do not need to be screened more often than other women, regardless of the method they use.

Screening women with a reproductive tract or sexually transmitted infection (RTI/STI)

Women in the target age group who present to health facilities with complaints suggestive of RTI/STI should be examined. They should be screened for cervical cancer only if there is no visible acute infection. If the speculum examination reveals evidence of acute infection, appropriate treatment should be given and cervical cancer screening should be deferred until after the infection has resolved.

Health education and counselling on RTI/STI should include information on HPV infection, its relation to cervical cancer, and the protection offered by safer sex behaviours, including condom use. Male partners too should be treated, and counselled on cervical cancer prevention. STI services aimed primarily at men should include information on HPV and cervical cancer prevention.

Other opportunities for cervical cancer screening

Women at the end of their reproductive years are at greatest risk of cervical cancer, particularly if they have never been screened. They tend to use reproductive health services less often than younger women, but may use other health services, e.g. for management of hypertension, heart disease, diabetes or infectious diseases. In addition, women in the target age group may come to a health facility with a child or relative who needs services. All women in the target age group who visit a facility for any reason should receive information and be encouraged to come for screening (see also Chapter 3). General medical services at primary, secondary and tertiary levels can provide cervical cancer screening for such women, using on-site, trained providers. If this is not possible, women should be given health education and referred to a convenient screening clinic.

No missed opportunities

Cervical cancer screening programmes should also try to reach all women in the target age group who have contact with the health system for any reason.

Choice of screening test to be used

The choice of screening test or tests to be used is usually made at the national or regional level. Nevertheless, providers should have some basic knowledge of all the available screening tests.

Decisions on the test or tests to be used may be based on:

- the organization of the health system;
- the funds available;
- the number and type of health workers;
- the availability of laboratory services and transport;
- the availability and cost of the various screening tests.

The test used may also be determined based on the physical proximity of services to women; for example, it might be decided to use the Pap smear (which requires women to return for their test results) in urban areas and visual inspection with acetic acid (VIA) (for which results are immediately available) in more inaccessible rural areas in the same country.

The most extensive and long-term experience in cervical cancer screening is with cytology, which has been used in numerous countries since the 1950s. Cytology-based screening and treatment programmes have reduced cervical cancer incidence and mortality by as much as 80% in Canada, the USA and some Nordic countries, and by 50–60% in other European countries.

It has been difficult to replicate this success in low-resource settings, because of the inherent requirements of a cytology-based programme. These include highly trained personnel, well equipped laboratories, transport of specimens, and an effective system for collecting information and following up patients. In addition, the demands of other competing health needs often result in a lack of resources or political will to make cervical cancer screening a priority.

Because of the problems of implementing quality cytology-based screening, alternative methods, such as visual inspection, have been developed. These methods have shown promise in controlled research settings but have not yet been widely implemented. Their ultimate impact on cervical cancer incidence and mortality will not be known until large ongoing population-based studies are completed. HPV-based tests are now also commercially available, but have disadvantages, including the need for sophisticated laboratory facilities and high cost.

Ethical issues

Decisions on how best to use scarce resources have to weigh the extent of disability and death caused by different diseases, and the efficacy, cost and impact of diagnosing and treating them. While decisions about priorities are usually made at national level, providers should understand the reasons for the decisions, so that they are motivated to implement them and can explain them to their patients (see Chapter 1). If well planned and integrated into other sexual and reproductive health activities, screening for cervical cancer has the potential to both strengthen the health care system and improve the health of women, particularly women over childbearing age, whose health is often relatively neglected.

Before a screening programme is implemented, the following elements should be considered to ensure an ethical and equitable approach:

- Screening should be accessible to all women in the target group, including the poorest, most vulnerable, and hardest to reach.
- Patients, providers and communities should receive health education to ensure informed decision-making on screening and treatment.
- Patient record systems should ensure confidentiality.
- Diagnostic tests, follow-up, and treatment should be available and accessible.
- Providers should have clear guidelines on follow-up and management of women with positive screening results.
- A referral system should be in place for other health problems, including gynaecological disorders, discovered during the screening process.

*Informed choice and Informed consent*⁷

Informed choice and informed consent are based on the ethical principles of autonomy and respect for the individual. In many cultures, the notion of consent may be a collective decision-making process involving others, such as partner, family, and village leaders. Accurate information provided through health education and counselling can ensure that women and their extended families understand the facts about cervical cancer, who is at risk, how screening can reduce risk, and any potential harm related to screening. Before consenting to screening, women should be given information on the specific test to be used, the meaning and consequences of a positive test, and the availability of treatment. In addition, when results are not available immediately (as they are with



Informed consent

⁷ *Note:* informed consent is not equivalent to informed choice. Consent refers to the explicit permission given by a person for a procedure or test, once she (or he) has received sufficient information to make a rational personal (informed) choice.

visual screening methods), informed consent should include explicit permission to be contacted at home or at work. Respect for autonomy requires that the choice to be screened is voluntary and free of coercion.

Client assessment

All clients attending for screening should have a basic assessment before proceeding to the screening test. This assessment should include information and counselling, informed consent, a social and clinical history, and a physical examination.



Counselling

The history can provide useful information for guiding decisions about management or additional examinations or tests that might benefit the patient. Because of the stigma associated with genital problems, women are often reluctant to talk about their concerns or symptoms and signs. To establish and maintain trust and respect, confidentiality and privacy must be explicitly guaranteed to each woman who presents for screening before she is asked about her history.

For cervical cancer screening, the essential components of the pelvic examination are visual inspection of the external genitals and a speculum examination. Providers should explain what is being done at each step during the examination; if an abnormality is noted, the provider should inform the woman without alarming her. Having female providers perform the physical examination, if possible, can greatly reduce reluctance to be examined and can play a major role in making screening acceptable. When the provider is a man, the woman may request that a female companion or clinic attendant is in the room.



Pelvic exam

Sexual and reproductive health problems detected during history-taking and examination

An integrated approach to management of sexual and reproductive health problems during screening can help improve the health of women, especially older women. The provider should pay particular attention to signs and symptoms suggestive of cancer, STI, or other diseases detected during history-taking and pelvic examination. In addition, women should be offered an opportunity to raise personal concerns regarding sexual and reproductive health issues. Women with abnormal findings can be treated or referred for further investigation, as appropriate.

Infection prevention in cervical cancer screening

In screening, as in all clinical activities, scrupulous attention should be given to infection prevention. Pathogens, including HIV, can be transmitted if guidelines on handwashing, handling of instruments, and disposal of used supplies, including gloves, are neglected.

Universal precautions (see Annex 1) against spreading infection should be used with all patients, whether they appear sick or well, and whether their HIV or other infection status is known or not. In this way, providers protect both their patients and themselves. Providers should use only uncontaminated instruments, and should wear latex gloves on both hands when performing speculum or bimanual examinations and taking specimens, and when performing procedures such as cryotherapy.



Infection prevention

SCREENING TESTS

A good screening test should be:

- accurate;
- reproducible;
- inexpensive;
- easy to perform and easy to follow up;
- acceptable;
- safe.

The following tests meet the above criteria to a greater or lesser extent:

- cytology: conventional (Pap smear) and liquid-based;
- HPV DNA test;
- visual inspection: with acetic acid (VIA) or Lugol's iodine (VILI).

The performance of each test is described below. The strengths and limitations of the different tests are summarized in Table 4.1. Measurement and interpretation of performance characteristics are outlined in Annex 3.



Test's performance

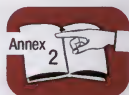
Cytology

Conventional Pap smear

In the Pap smear test, a sample of cells is taken from the transformation zone of the cervix using an extended-tip wooden spatula or brush; using a cotton swab is no longer recommended. The entire transformation zone should be sampled since this is where almost all high-grade lesions develop. The sample is then smeared onto a glass slide and immediately fixed with a solution to preserve the cells. The slide is sent to a cytology laboratory where it is stained and examined using a microscope to determine whether the cells are normal (Figure 4.1) and to classify them appropriately, using the Bethesda classification (see Annex 2). The results of the Pap smear are then reported to the clinic where the



Pap smear



Bethesda system

specimen was taken. Health workers are responsible for ensuring that the woman is informed of her result and that she receives appropriate follow-up as outlined in Annex 4a. The Pap test takes less than 5 minutes to perform, is not painful, and can be done in an outpatient examination room. It is advisable to postpone taking a Pap smear if the woman is menstruating actively, has a clinically evident acute inflammation, or is pregnant. A satisfactory smear requires adequate numbers of well preserved squamous epithelial cells and an adequate endocervical/transformation zone component. Each smear should be legibly labelled.

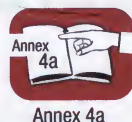
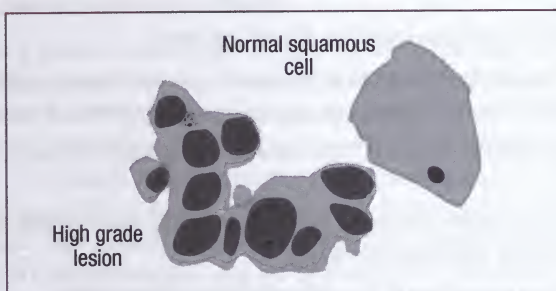


Figure 4.1 Graphic representation of normal and abnormal epithelial cells



The accuracy of cytological testing depends on the quality of the services, including sampling practices (taking and fixing the smears), and preparation and interpretation of smears in the laboratory. Under the best conditions in developed countries or research settings, conventional cytology can detect up to 84% of precancer and cancer. However, under poor conditions its sensitivity can be as low as 38%. The specificity of the test is usually over 90%.

Liquid-based cytology (LBC)

This refinement of conventional cytology was introduced in the mid-1990s and is increasingly used in high-resource settings. Instead of smearing cervical cells on a slide, the provider transfers the specimen from a brush to a preservative solution. The specimen is sent to a laboratory where the slide is prepared. LBC is more expensive than conventional cytology and laboratory staff need to be specially trained. However, it appears to have a number of advantages over conventional methods.

- The specimens obtained are more representative of the areas sampled with fewer false negatives.
- There are fewer unsatisfactory specimens.
- Each specimen requires a shorter interpretation time, leading to increased efficiency and cost-effectiveness.
- The material collected can also be tested for HPV DNA.

Although, as yet, no randomized controlled trial comparing LBC with conventional Pap smear has been published, several studies have shown that LBC is more sensitive than Pap smear and has almost the same specificity.

Providers

After a short training course, any provider who knows how to do a speculum examination (nurse, auxiliary or assistant nurse, midwife, clinical officer, medical doctor) can take a Pap smear.

Indications

The following groups of women should be offered screening:

- Any woman between the ages of 25 and 65 years, who has never had a Pap smear before or who had one 3 or more years ago (or according to national guidelines).
- Women whose previous Pap smear was reported as inadequate or showed a mild abnormality.
- Women who have abnormal bleeding, bleeding after intercourse or after the menopause, or other abnormal symptoms.
- Women who have been found to have abnormalities on their cervix.

Interpretation of smears

Smears are read in a laboratory by trained cytotechnicians, under the supervision of a pathologist, who has final responsibility for the reported results. Correct interpretation of slides is crucial to a successful programme. To maintain proficiency and avoid fatigue, cytotechnicians should spend a maximum of 5 hours a day at the microscope and should review a minimum of 3000 slides per year. Quality assurance is crucial and should be established in all cytology laboratories. The two most commonly used methods are rapid review of all negative slides, and full rescreening of a 10% random sample of slides originally reported as negative. In both methods, the review is done by another cytotechnician, with confirmation of abnormal smears by the supervising pathologist. Current evidence shows that, of the two methods, rapid review of all negative smears is more effective and more cost-effective. Laboratories should be equipped to read a minimum of 15 000 smears annually.⁸ Therefore, cytology services should not be decentralized to primary health care clinics or to small laboratories. Reliable transport of slides and test results to and from the laboratory is essential.

⁸ Detailed information on cytology laboratories is beyond the scope of this Guide. Further information can be found in the references listed under "Additional resources" at the end of this chapter.

The speed with which results are sent to the health facility is an important element of the quality of the laboratory service and the quality of care, and greatly affects women's satisfaction with the service.

RECOMMENDATION

Cytology is recommended for large-scale cervical cancer screening programmes, if sufficient resources exist.

HPV DNA-based screening methods

New screening procedures are based on the detection of high-risk HPV DNA in vaginal or cervical smears. A sample of cells is collected from the cervix or vagina using a swab or small brush, and placed in a small container with a preservative solution. The specimen can be collected by a health care provider or by the woman herself, inserting a swab deep into the vagina. Studies comparing the two collection methods have shown that self-collection is less sensitive than provider-collection. In either case, the specimen containers are transported to a laboratory where they are processed. HPV DNA-based tests currently require sophisticated and expensive laboratory equipment, although work is under way to develop a more affordable and less complicated test that can be carried out in lower-level settings. Detection of high-risk HPV does not necessarily mean that precancer or cancer is present; it indicates simply that there is an HPV infection. As mentioned earlier, HPV infections are extremely common in women under 35 years, and most of them resolve spontaneously. When detection of HPV is used as a primary screening test, the sensitivity for detection of precancer and cancer varies from 50% to 95%, with most studies reporting high sensitivity of 85% or more. The specificity ranges from 50% to 95%, with an average of 84%. In women aged 35 years or older, HPV DNA tests perform better because in these women a positive test is more likely to be due to a persistent infection than in younger women. The average sensitivity and specificity in this group are 89% and 90%, respectively. The combination of cytology and HPV testing has very high sensitivity and negative predictive values approaching 100% (see Annex 3). It might therefore be possible to increase the interval between screenings for women who are negative on both tests. However, performing the two tests together is expensive. The high cost, and the need for both a molecular laboratory and reliable methods of transport, present major challenges, and the feasibility of HPV testing has not been demonstrated in low-resource settings. A new, faster, highly sensitive and less costly test for HPV is under development but is not yet available.



Providers

HPV DNA testing can be done by trained providers at any level of the health care system, provided that there is an appropriate laboratory within a reasonable distance, and that reliable transport is available for specimens. Clinic needs for HPV testing are the same as for Pap smears and visual methods.

Indications

HPV is not generally used on its own as the primary screening test. It is mainly used in combination with cytology to improve the sensitivity of the screening or as a triage tool to assess which women with borderline Pap results need to be referred for colposcopy. The main indication is a Pap result of “atypical cells of undetermined significance” (ASC-US). Of the women with this lesion, only those who test positive for high-risk HPV will need to be referred for colposcopy and biopsy, significantly reducing the number of colposcopies.

Laboratory facilities

The HPV laboratory requires a special clean room to avoid contamination, and highly trained technicians. It also requires equipment and reagents as specified by the manufacturers of the test.

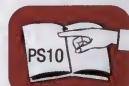
RECOMMENDATION

HPV DNA tests as primary screening methods, at this time, are recommended for use only in pilot projects or other closely monitored settings. They can be used in conjunction with cytological or other screening tests, where sufficient resources exist. HPV DNA-based screening should not begin before 30 years of age.

Visual methods

Two visual methods are available:

- visual inspection with acetic acid (VIA);
- visual inspection with Lugol's iodine (VILI).



VIA and VILI

Abnormalities are identified by inspection of the cervix without magnification, after application of dilute acetic acid (vinegar) (in VIA) or Lugol's iodine (in VILI). When vinegar is applied to abnormal cervical tissue, it temporarily turns white (acetowhite) allowing the provider to make an immediate assessment of a positive (abnormal) or negative

(normal) result. If iodine is applied to the cervix, precancerous and cancerous lesions appear well-defined, thick, and mustard or saffron-yellow in colour, while squamous epithelium stains brown or black, and columnar epithelium retains its normal pink colour.

Because they do not rely on laboratory services, VIA and VILI are promising alternatives to cytology where resources are limited. They are currently being tested in large, cross-sectional, randomized controlled trials in developing countries. Until data from these studies are available, VIA and VILI are recommended by WHO only for use in pilot settings, because the impact on cervical cancer incidence and mortality is still unproven. In research settings, VIA has been shown to have an average sensitivity for detection of precancer and cancer of almost 77%, and a range of 56% to 94%. The specificity ranges from 74% to 94% with an average of 86%. Low-level magnification does not improve the performance of VIA over and above that of naked eye visualization. One study has shown that VILI can detect 92% of women with precancer or cancer, a sensitivity considerably higher than that of either VIA or cytology. Its ability to identify women without disease is similar to that of VIA (85%), and lower than that of Pap smears. One study showed that VILI had a higher reproducibility than VIA. VIA and VILI can be performed in clinics and other outpatient facilities. They are both short procedures and cause no pain. Assessment is immediate, and no specimen is required.

Advantages

- VIA and VILI are relatively simple and can be taught to nurses, nurse-midwives and other health workers.
- Assessment is immediate and no transport, or laboratory equipment or personnel, is needed.
- The tests are likely to be less costly than other approaches in routine use.
- Results are available immediately, eliminating the need for multiple visits in most cases, and reducing loss to follow-up.
- They could potentially be used in an approach based on screening and treating women in a single visit (see Chapter 5).

Disadvantages

- Because of the low positive predictive value of the test (see Annex 3), a considerable number of women who test positive do not have disease, resulting in excessive diagnosis and treatment, and unnecessary anxiety.
- Visual tests cannot be relied on in postmenopausal women, because the transformation zone of these women is often inside the cervical canal.



Annex 3

- There is no permanent record of the test that can be reviewed later.
- VIA has mostly been evaluated as a once-in-a-lifetime screening test, and its performance in periodic screening has not been assessed.

Providers

Trained nurses, nurse-midwives, nurse assistants, physicians and other health workers with adequate and ongoing support and supervision can perform VIA. Training takes 5–10 days using a competency-based approach. To maintain quality services, it is important that an experienced provider conducts regular assessments. Studies show that immediately after training, providers have more false positive results. These decrease in a few months as the providers gain experience.

Indications

If adopted by a programme as a screening method, VIA and VILI are indicated for all women in the target age group specified in national guidelines, provided that:

- They are premenopausal. Visual methods are not recommended for postmenopausal women, because the transition zone in these women is most often inside the endocervical canal and not visible on speculum inspection.
- Both squamocolumnar junctions (i.e. the entire transformation zone) are visible.

If the patient does not meet the above indications and no alternative screening method is available in the particular clinical setting, she should be referred for a Pap smear.

RECOMMENDATION

Visual screening methods (VIA and VILI), at this time, are recommended for use only in pilot projects or other closely monitored settings. These methods should not be recommended for postmenopausal women.

Table 4.1 Summary of characteristics of screening methods for cervical cancer

Test	Procedure	Strengths	Limitations	Status
Conventional cytology (Pap smear)	Sample of cervical cells taken by provider and examined by trained cytotechnicians in a laboratory	• History of long use • Widely accepted • Permanent record of test • Training and mechanisms for quality control established • Modest investments in existing programmes can improve services • High specificity	• Results not immediately available • Systems needed to ensure timely communication of test results and follow-up of women • Transport required for specimen to laboratory and for results to clinic • Requires laboratory quality assurance • Moderate sensitivity	• Available in many countries since the 1950s • Cytology-based programmes have reduced cancer mortality in developed countries
Liquid-based cytology (LBC)	Sample of cervical cells is obtained with a small brush, immersed in special liquid and sent to laboratory for processing and screening	• Fewer inadequate or unsatisfactory samples requiring patient call-back and rescreening • Once cytotechnicians are proficient, LBC samples take less time to review • Samples can be used for molecular testing (such as for HPV)	• Results not immediately available • Supplies and laboratory facilities more expensive than for conventional cytology • No controlled studies, to date, comparing sensitivity and specificity with conventional cytology	Selected as screening method in some developed countries (e.g. United Kingdom)

continued next page

Continued from page 99

Table 4.1 Summary of characteristics of screening methods for cervical cancer

Test	Procedure	Strengths	Limitations	Status
HPV DNA testing	Molecular testing for HPV – swab taken by provider or woman herself and sent to laboratory	• Collection of specimen simple • Automated processing • Can be combined with Pap smear to increase the sensitivity, but this increases also the cost • A negative test means no HPV and related morbidity is present • The assay result is a permanent record • High specificity in women over age 35	• Results not immediately available • High unit cost • Complex laboratory requirements and specimen transport • Low specificity in young women leading to overtreatment • Storage of reagents problematic	• Commercially available and used in some developed countries in addition to cytology • Lower-cost tests in development
Visual methods (VIA and VILI)	Trained provider examines cervix after staining with vinegar (in VIA) and with Lugol's iodine (in VILI)	• Relatively simple and inexpensive • Results available immediately • Can be performed by wide range of personnel after short training • Low level of infrastructure required • Can be combined with offer of immediate treatment in single-visit approach	• High provider variability • Lower specificity resulting in high referral rate and overtreatment • No permanent record of test • Not appropriate for postmenopausal women • Lack of standardization • Frequent retraining needed	• Limited evidence available • Only recommended at this time for use in demonstration projects • Large randomized controlled trials under way to determine effect on cancer incidence and mortality

FOLLOW-UP

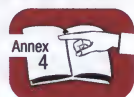
Follow-up and management of women with an abnormal (positive) test

Screening by itself will not prevent a single case of cervical cancer. An effective system for follow-up and treatment of women who test positive is perhaps the most important component of a successful cervical cancer prevention programme.

Ideally, all women should receive the results of their test, whether negative or positive. In practice, resources will sometimes be too limited to allow this.

At the very least, women whose test result is positive or abnormal must be informed of the result and of what follow-up is needed.

Follow-up should be in line with national protocols or based on the recommendations found in Annex 4.



Flowchart screening

Follow-up is essential for the woman's welfare and for the success of the programme and every effort should be made to contact women with positive test results.

The following actions will help ensure that women with an abnormal screening test can be reached for follow-up:

- The woman's address, or other information on how she can be reached, should be noted at the time of screening (with her consent).
- During counselling and after screening, providers need to emphasize the importance of coming back for results and follow-up care.
- Every clinic should have a directory of all women with abnormal test results, with an indication of whether they have received the results and been followed up. Clinics should designate someone to ensure that follow-up is done.

For women who do not return spontaneously as advised, providers can:

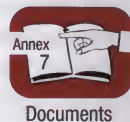
- send a letter by mail;
- telephone women at home or at work;
- ask community health workers to contact women directly at home.

Health care managers and providers can develop other locally appropriate approaches to reach women with abnormal screening tests.

Health facilities need to make every effort to find women with abnormal results if they do not return for scheduled appointments.

Record-keeping

Records should be compatible throughout a country, so that all the data collected by the cervical cancer control programme can be compared. The information system should include every woman's clinical record, appointments scheduled, and those kept or missed. This can be a simple paper record or can be computer-based. A logbook can be used to register women screened and record their test results. If women need to return later for their results, a system must be in place to ensure that those with abnormal results are notified and that women who are hard to locate are traced. Sample forms for follow-up can be found in Annex 7.



SCREENING ACTIVITIES AT DIFFERENT LEVELS OF THE HEALTH SYSTEM

In the community



- Educate and inform the community, promote the screening programme, and encourage women to attend.
- Refer appropriate women for screening.
- Assist women to attend screening clinics.
- Assist in follow-up of women with a positive screening to ensure that they return to the clinic for management.

At the health centre



- Screen, using methods specified by national guidelines and integrating screening into other services.
- Train, support and supervise CHWs.
- Work with CHWs to educate women, and recruit them for screening.
- Participate in campaigns to bring women at high risk for testing.
- Provide counselling and health education in the clinic and community.
- Inform and counsel women with positive screening test results, and advise them on needed follow-up, diagnosis and treatment.
- Implement an accurate patient information system, to allow proper tracking and follow-up of women after treatment.

At the district hospital



- Carry out screening activities as per national programme.
- Inform and counsel women with positive screening test results, and advise them on needed follow-up, diagnosis and treatment.
- Train, support and supervise providers at health centre level.
- Manage referral systems with lower and higher levels of the health system.

At the central hospital



- Carry out screening in outpatient clinics where women are seen.
- Maintain central cytology, pathology, and molecular laboratories, as feasible.
- Interpret screening and histopathology results and ensure that results reach the screening site.
- Train medical personnel, and support and supervise providers in lower-level health facilities.
- Manage referral and links with lower levels of the health system.

Counselling messages

4

Women who have just had a screening test need to be told:

- if anything abnormal was noted;
- when the results will be available;
- the date of the next appointment.

Women returning for test results should be counselled on:

- the result of the test and what it means;
- if normal, when they need to return for repeat screening;
- if inadequate or not normal, what follow-up is needed;
- where and when to go for follow-up.

ADDITIONAL RESOURCES

- ACCP. *Planning and implementing cervical cancer prevention programs: a manual for managers*. Seattle WA, Alliance for Cervical Cancer Prevention, 2004.
- Arbyn M. *A technical guideline: collection of adequate Pap smears of the uterine cervix*. Brussels, Scientific Institute of Public Health, 2001.
- *Cervical cancer prevention: guidelines for low-resource settings*. Baltimore, MD, JHPIEGO Corporation, 2001.
- CHIP. *Implementing cervical screening in South Africa. Volume I. A guide for programme managers*. New York, Cervical Health Implementation Project, South Africa, University of Cape Town, University of the Witwatersrand, EngenderHealth, 2004.
- IARC. *A practical manual on visual screening for cervical neoplasia*. Lyon, IARC Press, 2003.
- IARC. *Cervix cancer screening*. Lyon, IARC Press, 2005 (IARC Handbooks of Cancer Prevention, Volume 10).
- *Infection prevention: a reference booklet for health care professionals*. New York, EngenderHealth, 2001.
- *Infection prevention curriculum: a training course for health care providers and other staff at hospitals and clinics*. New York, EngenderHealth, 1999.
- Miller AB. *Cervical cancer screening programmes, managerial guidelines*. Geneva, WHO, 1992.
- PATH. *Planning appropriate cervical cancer prevention programs*. Seattle, WA, Program for Appropriate Technology in Health, 2000.
- PATH VIA/VILI curriculum. Course in visual methods for cervical cancer screening. In: Tsu V et al., *Western Kenya Cervical Cancer Prevention Project Final Report*. Seattle, WA, Program for Appropriate Technology in Health, 2004 (Annex 10).
- Salas Diehl I, Prado Buzeta R, Muñoz Magna R. *Manual de Procedimientos de Laboratorio de Citología*. Washington, DC, Organización Panamericana de la Salud, 2002.
- WHO. *Cervical cancer screening in developing countries. Report of a WHO Consultation*. Geneva, 2002.

ORIGINAL ARTICLES	SYMPOSIUM
114-118 Effect of a Low-Fat Diet on the Plasma Lipid Profile in Patients with Coronary Heart Disease J. H. Anderson, M.D., and J. H. Anderson, M.D.	119-122 Coronary Artery Disease: A Review of the Literature J. H. Anderson, M.D., and J. H. Anderson, M.D.
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PRACTICE SHEET 6: OBTAINING INFORMED CONSENT

PS6

Practice Sheet 6: Obtaining Informed Consent

WHAT IS INFORMED CONSENT?

Women must give informed consent before being screened for cervical cancer. This means that she should understand what is to take place, including the potential risks and complications of both proceeding and not proceeding, and has given permission for the procedure. It should be made clear to the woman that there will be no punitive action if she refuses the procedure.

When asking for informed consent:

- Give the woman all essential information on what you are about to do and request her consent before starting any examination or procedure. It is unethical to ask for informed consent retroactively.
- If there is a possibility that she might need to be contacted at home or at work (e.g. to give test results or remind her to return for an appointment), obtain consent for doing so.
- Family members should be included in the discussion only if the woman has given explicit permission.
- Keep medical terminology to a minimum. Explain any technical words that have no local equivalent.
- You may find it helpful to draw or use pictures to illustrate your explanations.
- Be clear and direct; do not use words the patient will not understand, or which are vague, such as “growth” or “neoplasm”.
- Do not confuse the woman by saying too much, but cover all the important issues.
- Allow some time for the woman to take in what you have said. Then let her ask questions. When all the questions have been addressed, ask the woman for her formal consent.
- It might be culturally important to include others, such as the woman’s partner, in the decision-making process; however, you should ensure that the woman’s wishes are respected.

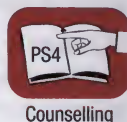
EXPLAINING PRACTICES AND PROCEDURES

You will find explanations for patients included in each chapter of this Guide and in the practice sheets. You may adapt these to individual situations to help explain procedures in terms the patient and her family understand.

STEPS FOR OBTAINING INFORMED CONSENT

Preparation

1. Ensure privacy and explain that confidentiality is always respected in your facility.
2. Follow your facility's regulations on obtaining informed consent.
3. Apply general rules on counselling and good communication. Listen carefully and address the woman's concerns; give her the time she needs to understand and to make a decision.
4. Ask her if she would like to have family members present or if she would like to discuss the decision with family members at home. Do not pressure her to make a decision before she is ready.



Process

5. Give all the necessary information on the test, procedure or treatment you are recommending and any available alternatives. Use the explanations for patients included in this Guide, adapted to your facility and the individual situation, to help explain procedures such as cryotherapy, surgery, and radiotherapy. Include the following information:
 - purpose of the procedure;
 - possible benefits;
 - risks of doing what you suggest and of not doing it;
 - need for anaesthesia or hospitalization;
 - potential side-effects and complications and what to do if any of them occur;
 - recovery time;
 - cost;
 - chance of success or failure.
6. Ask the woman if she has any questions, and answer them.
7. Check that the patient has understood. You can do this by asking her to repeat points that may be difficult or important, or by using other words to reiterate the most important issues, such as: "Did you understand that you should not have intercourse for 4 weeks after this procedure? How do you think your husband will feel about that?"
8. Correct any misunderstanding.
9. Keep a written record, either on a consent form or in the medical record (according to your facility's guidelines), that:
 - you confirmed her understanding of the information;
 - her decision to undergo a test or treatment (or to refuse it) was voluntary.

PRACTICE SHEET 7: TAKING A HISTORY AND PERFORMING A PELVIC EXAMINATION⁹

PS 7

Cervical cancer screening includes taking a history, to assess if the woman has specific risk factors or suggestive symptoms. Most screening tests involve a speculum examination.

The following equipment and supplies should be available:

- clinical chart and pencil;
- drawings of pelvic organs, if possible;
- soap and water for washing hands;
- light source to examine the cervix;
- examination table covered by clean paper or cloth;
- disposable or high-level disinfected examination gloves;
- specula of different sizes, high-level disinfected (need not to be sterile);
- small container of warm water to lubricate and warm the speculum;
- 0.5% chlorine solution for decontaminating instruments and gloves.

HISTORY

Ask the patient about:

- her age, education, number of pregnancies, births and living children, last menstrual period, menstrual pattern, previous and present contraception;
- previous cervical cancer screening tests, their dates and results;
- medical history including any medications or drug allergies;
- social history, including factors that may increase her risk of cervical cancer;
- sexual history including age of sexual initiation and of first pregnancy, number of partners, previous STIs, and any behaviours that may suggest an increased risk of cervical cancer;
- any symptoms and signs of cervical cancer and other illnesses.

⁹ Adapted from: Burns A et al. Where women have no doctor. Berkeley, CA, Hesperian Foundation, 1997; and WHO. *Sexually transmitted and other reproductive tract infections: a guide to essential practice*. Geneva, 2005.

PS 7

PERFORMING A PELVIC EXAMINATION

After taking a history, perform a pelvic examination. There are three components to the female genital examination:

- an external genital examination;
- a speculum examination;
- a bimanual examination.

Before the examination

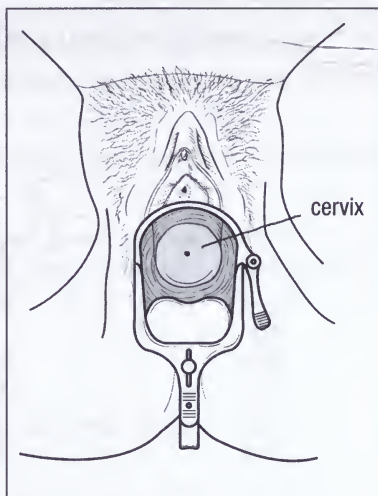
1. Have all necessary equipment and supplies ready. Ensure the speculum used is at a comfortable temperature.
2. If tests or interventions are planned (e.g. a Pap smear), tell the woman what they are, what they are for, and when you expect to have the results.
3. Ask the woman if she has any questions, and answer them truthfully.
4. Explain what the pelvic examination consists of and show the woman a speculum.
5. Ask the woman to empty her bladder (urinate) and have her undress from the waist down. Be particularly sensitive to her sense of modesty about uncovering normally clothed areas, or if the examination is perceived to be invasive.
6. Position the woman on the examination table.

Examination of the external genital area

7. Using a gloved hand to gently touch the woman, look for redness, lumps, swelling, unusual discharge, sores, tears and scars around the genitals and in between the skin folds of the vulva. These can be signs of a sexually transmitted infection.

The speculum examination

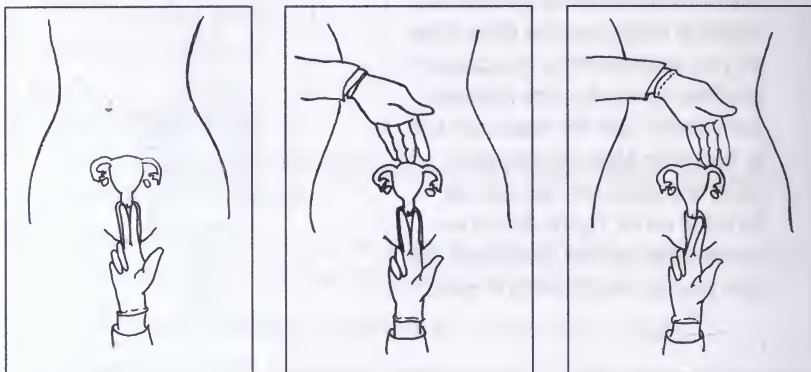
8. Hold the speculum blades together sideways and slip them into the vagina. Be careful not to press on the urethra or clitoris because these areas are very sensitive. When the speculum is halfway in, turn it so the handle is down. Gently open the blades and look for the cervix. Move the speculum slowly and gently until you can see the entire cervix. Tighten the screw (or otherwise lock the speculum in the open position) so it will stay in place.



9. Check the cervix, which should look pink, round and smooth. There may be small yellowish cysts, areas of redness around the opening (cervical os) or a clear mucoid discharge; these are normal findings.
10. Look for any abnormalities, such as:
 - a. Vaginal discharge and redness of the vaginal walls, which are common signs of vaginitis. If the discharge is white and curd-like, there is probably a yeast infection.
 - b. Ulcers, sores or blisters. Genital ulcers may be caused by syphilis, chancroid, herpes virus or, in some cases, cancer. Sores and blisters are usually caused by herpes virus.
 - c. Easy bleeding when the cervix is touched with a swab, or a mucopurulent discharge, which are signs of a cervical infection.
 - d. An abnormal growth or tumour, which might be cervical cancer.
11. Gently pull the speculum towards you until the blades are clear of the cervix, close the blades and remove the speculum.

The bimanual examination

The bimanual examination allows you to feel the reproductive organs inside the abdomen.



12. Test for cervical motion tenderness. Put the pointing and the middle finger of your gloved hand in the woman's vagina. Turn the palm of your hand up. Feel the cervix to see if it is firm and round. Then put one finger on either side of the cervix and move the cervix gently while watching the woman's facial expression. If this causes pain (you may see the woman grimace), this indicates cervical motion tenderness, and she may have an infection of the womb, tubes or ovaries (pelvic inflammatory disease or PID). If her cervix feels soft, she may be pregnant.
13. Feel the womb by gently pushing on her lower abdomen with your other hand. This moves the womb, tubes and ovaries closer to the fingers inside her vagina. The womb may be tipped forwards or backwards. When you find the womb, feel for its size and shape. It should feel firm, smooth and smaller than a lemon.
 - If the womb feels soft and large, the woman is probably pregnant.
 - If it feels lumpy and hard, she may have a fibroid or other growth.
 - If it hurts her when you touch it, she may have an infection.
 - If it does not move freely, she may have scars from an old infection.

14. Feel the tubes and ovaries. If these are normal, they will be hard to feel. If you feel any lumps that are bigger than an almond or that cause severe pain, she may have an infection or other condition needing urgent treatment. If she has a painful lump, and her period is late, she may have an ectopic pregnancy; in this case, she *needs medical help* right away.
15. Move your finger to feel the inside of the vagina. Make sure there are no unusual lumps, tears or sores.
16. Ask the woman to cough or push down as if she were passing stool. Look to see if something bulges out of the vagina. If it does, she may have a fallen womb or fallen bladder (prolapse).

After the examination

17. Place used equipment and gloves in decontamination solution.
18. Wash your hands with soap and water.
19. Record all findings on the woman's chart.
20. Tell the woman if her examination was normal or if you noted anything unusual or abnormal, and explain what any abnormality you noted might mean.
21. If you noted any signs that might indicate a sexually transmitted infection, treat the woman and her partner immediately, according to national or WHO guidelines.¹⁰ Provide condoms and teach them how to use them. If you found an acute cervical infection or PID, provide treatment as outlined in Annex 8.
22. If you found something that needs urgent treatment or that cannot be handled at your centre (e.g. ectopic pregnancy, prolapse, cervical tumour), refer the woman to a higher level of care.
23. Give her a date to return for follow-up if necessary.



¹⁰ WHO. *Sexually transmitted and other reproductive tract infections: a guide to essential practice*. Geneva, 2005.

PS7

Practice Sheet 7: Taking a History and Performing a Pelvic Examination

PRACTICE SHEET 8: TAKING A PAP SMEAR

PS 8

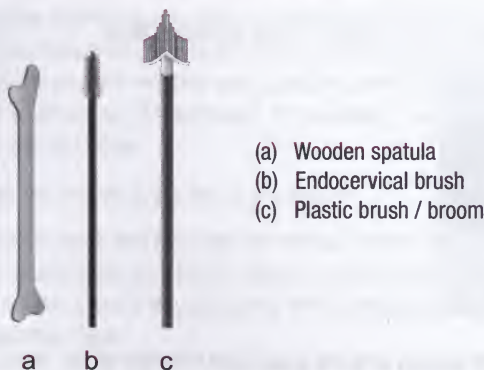
PS 8: Taking a Pap Smear

In a Pap smear test, a sample of cells is taken from the uterine cervix using a spatula or brush (see figure PS8.1), smeared onto a slide, and examined under a microscope for abnormal cells (precancer or cancer). When a Pap smear shows abnormal epithelial cells, it is reported as positive. Most women with a positive Pap smear need more tests to confirm the diagnosis and to determine whether treatment is needed.¹¹

The following materials and equipment are needed for taking a conventional Pap smear:

- soap and water for washing hands;
- a light source to examine the cervix;
- an examination table covered by clean paper or cloth;
- a speculum, high-level disinfected (it need not be sterile);
- disposable or high-level disinfected examination gloves;
- an extended-tip wooden or plastic spatula (or another device for sampling);
- a glass slide with frosted edge and pencil for labelling;
- fixative solution;
- recording form;
- small container of warm water to lubricate and warm the speculum;
- 0.5% chlorine solution for decontaminating instruments and gloves.

Figure PS8.1 Devices for Pap smear sampling



¹¹ When the Pap smear reports ASC-US or LSIL, only persistent lesions (reported on two Pap smears within 6 months to 1 year) should be investigated further.

PS 8

TAKING A PAP SMEAR

Note the following:

- It is best not to take a smear from women who are actively menstruating or have symptoms of an acute infection. Slight bleeding is acceptable.
- Pregnancy is not an ideal time for a Pap smear, because it can give misleading results. However, if the woman is in the target age group and it is likely that she will not return after giving birth, proceed with the smear.

Use Practice Sheet 4 to give counselling before doing any examination, test or procedure. Counselling steps specific to taking smears are included in the steps below.



Counselling

Preparation

1. Explain the procedure, what the test results mean, and why it is important to return for the test results and act on them appropriately. Ensure that the woman has understood and obtain informed consent.
2. Do a speculum examination as described in Practice Sheet 7.



Informed consent

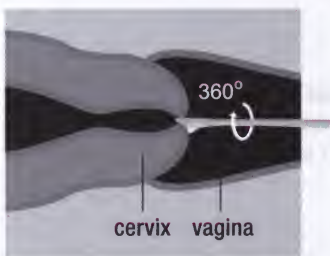


PS7 Pelvic exam

Taking the smear with a wooden spatula

3. Insert the long tip of the spatula into the os, and rotate it through a full circle (360 degrees).

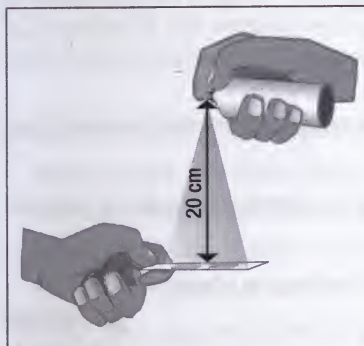
Figure PS8.2 Taking a sample of cervical cells with a wooden spatula



4. Smear both sides of the spatula onto the glass slide with one or two careful swipes. If you see any abnormalities outside the area sampled, take a separate specimen and smear it on another slide.

5. Immediately fix each slide. Either use spray fixative, at a right angle to, and a distance of 20 cm from, the slide, or immerse the slide in a container of 95% ethanol for at least 5 minutes.

Figure PS8.3 Fixing a conventional Pap smear



If the slide is not fixed immediately, the cells will dry and become misshapen; it will then not be possible to read the slide accurately in the laboratory.

6. Gently close and remove the speculum.
7. Place all used instruments in decontamination solution.

After taking the smear

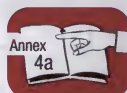
8. Label the frosted edge of each slide carefully with the woman's name and clinic record number, and the date.
9. On the patient record, note and illustrate any features you have noted: visibility of the transformation zone, inflammation, ulcers or other lesions, abnormal discharge. Note whether other samples were taken, for example Pap smear of other areas, any STI tests and, if the woman has been referred elsewhere, to whom and when.
10. Ask the woman if she has any questions.
11. Tell her when and how she will receive the test results and stress the importance of returning for her results. Ideally, results should be sent to the clinic within 2 or 3 weeks. It is not acceptable for the laboratory to take more than 1 month before reporting back.

PS8

12. If you saw something for which you wish to refer the woman to a higher level, explain why, where and when she must go, and whom to see; stress the importance of keeping this appointment.
13. Suggest to the woman that she encourage family members and friends in the target age group to come in for a Pap smear.

Follow-up

14. When the woman returns, give her the test results, explain what they mean, and advise what needs to be done.
 - If the test is negative (normal), tell her to have another test within 3 years (or as per national guidelines).
 - In the other cases, use the flowchart in Annex 4a to advise the woman on how she should be followed up.



Flowchart PAP

15. If the woman does not return, and her smear was abnormal or inadequate, try to contact her. A sample letter to send to such patients is given in Annex 7. Other strategies to ensure return are described in Chapter 4.



Documents

Your task is not completed until each woman has been told her test results, or at least those women with abnormal test results.

PRACTICE SHEET 9: COLLECTING SAMPLES FOR HPV DNA TESTING

For HPV DNA testing, secretions are collected from the cervix or vagina using a swab or small brush, and placed in a special liquid to be sent to the laboratory. There they can be tested for HPV infection, which can stimulate changes in the cells covering the cervix. The test does not diagnose cervical precancer or cancer.

The following materials and supplies are needed to collect samples for HPV testing:

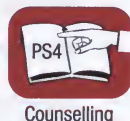
- soap and water for washing hands;
- a light source to examine the cervix;
- an examination table covered by clean paper or cloth;
- a speculum, high-level disinfected (it need not be sterile);
- disposable or high-level disinfected examination gloves;
- small brush or soft swab;
- small container with preservative solution;
- recording form;
- small container of warm water to lubricate and warm the speculum;
- 0.5% chlorine solution for decontaminating instruments and gloves.

TAKING A SAMPLE FOR HPV TESTING

Note the following:

- It is best not to take a sample from women who are actively menstruating. Slight bleeding is acceptable.
- HPV testing, if available, is most useful when done in conjunction with a cytological test, in women aged 35 years or older.

Use Practice Sheet 4 to give counselling before doing any examination, test or procedure. Counselling steps specific to the HPV test are included in the steps below.



Preparation

1. Explain what an HPV test is and what a positive test means. Ensure that the woman has understood and obtain informed consent.
2. Do a speculum examination as described in Practice Sheet 7.



PS7 Pelvic exam

Taking the sample

3. Take a smear from the top of the vagina and the cervical os using a brush or swab.
4. Place the brush or swab in a special container with preservative solution.
5. Gently close and remove the speculum.
6. Place all used instruments in decontamination solution.
7. Label the container with the woman's name and clinic record number, and the date.

After taking the specimen

8. Tell the patient about anything unusual you noted.
9. Record your observations and the taking of the sample on the patient chart.
10. Tell the woman when she should return for the test results.
11. If you saw something for which you wish to refer the woman to a higher level, explain why, where and when she must go, and whom to see; stress the importance of keeping this appointment.

Alternative method: self-collection

1. Explain to the woman how to collect her own specimen, as per instructions of the manufacturer of the test kit.
2. Provide her with swabs and a vessel with preservative solution.
3. She can collect the specimen in the clinic, if there is a private area, or at home.
4. If she collects the specimen at home, she should bring it to the clinic as soon as possible, and in any case within the time specified by the manufacturer of the test kit.
5. Send the specimen to the special laboratory for examination.

Follow-up

12. When the woman returns, whether the specimen was collected by herself or by the provider, give her the test result, explain what it means, and if necessary advise her on any additional tests or treatment needed.
13. If the test was used as a primary screening tool, women with a positive test should be referred for colposcopy. If the test was done in conjunction with a Pap smear, whose result was ASC-US, only women positive for high-risk HPV need to be referred for colposcopy and biopsy.
14. Be prepared to respond to questions concerning the implications of a positive HPV test.



FAQs

PS 9

PS9

Practice Sheet 9: Collecting Samples for HPV DNA Testing

PRACTICE SHEET 10: VISUAL SCREENING METHODS

PS 10

Practice Sheet 10: Visual Screening Methods

In a visual test, the provider applies acetic acid (in VIA) or Lugol's iodine solution (in VILI) to the cervix, and then looks to see if there is any staining. A VIA test is positive if there are raised and thickened white plaques or acetowhite epithelium; a VILI test is positive if there are mustard or saffron-yellow coloured areas, usually near the SCJ. Either test is suspicious for cancer if a cauliflower-like fungating mass or ulcer is noted on the cervix. Visual screening results are negative if the cervical lining is smooth, uniform and featureless; it should be pink with acetic acid and dark brown or black with Lugol's iodine.

The following materials and equipment are needed for visual methods:

- soap and water for washing hands;
- a bright light source to examine the cervix;
- a speculum, high-level disinfected (it need not be sterile);
- disposable or high-level disinfected examination gloves (need not be sterile);
- examination table covered by clean paper or cloth;
- cotton-tipped swabs;
- dilute acetic acid solution (3–5%) or white vinegar;
- Lugol's iodine solution;
- 0.5% chlorine solution for decontaminating instruments and gloves;
- recording form.

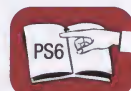
PERFORMING VISUAL SCREENING TESTS

Note the following:

- Visual methods are not recommended for use in postmenopausal women, because their transition zone is most often inside the endocervical canal and not visible on speculum inspection.

Preparation

1. Explain the procedure, how it is done, and what a positive test means. Ensure that the woman has understood and obtain informed consent.
2. Do a speculum examination as described in Practice Sheet 7.



Informed consent



PS7 Pelvic exam

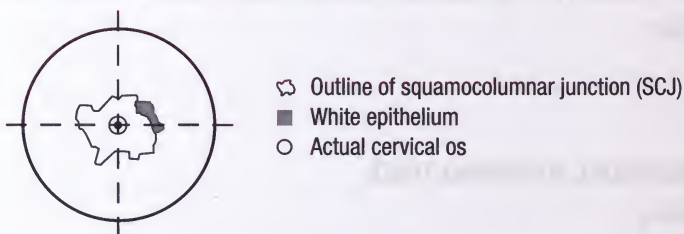
PS10

Performing the test

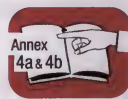
3. Adjust the light source in order to get the best view of the cervix.
4. Use a cotton swab to remove any discharge, blood or mucus from the cervix.
5. Identify the SCJ, and the area around it.
6. Apply acetic acid or Lugol's iodine to the cervix; wait a minute or two to allow colour changes to develop. Observe any changes in the appearance of the cervix. Give special attention to abnormalities close to the transformation zone.
7. Inspect the SCJ carefully and be sure you can see all of it. Report if the cervix bleeds easily. Look for any raised and thickened white plaques or acetowhite epithelium if you used acetic acid or saffron-yellow coloured areas after application of Lugol's iodine. Remove any blood or debris appearing during the inspection.
8. Use a fresh swab to remove any remaining acetic acid or iodine solution from the cervix and vagina.
9. Gently remove the speculum.

After screening

10. Record your observations and test result. Draw a map of any abnormal findings on the record form.

Figure PS10.1 VIA results recorded on labelled drawing

11. Discuss the results of the screening test with the patient. If the test is negative, tell her that she should have another test in three years. If the test is positive or cancer is suspected, tell her what the recommended next steps are (see Annex 4a for standard approach and Annex 4b for the screen-and-treat approach). If she needs to be referred for further testing or treatment, make arrangements and provide her with all necessary forms and instructions before she leaves. If you can make the appointment immediately, do so.



Annex 4a & 4b

5

CHAPTER 5: DIAGNOSIS AND MANAGEMENT OF PRECANCER

CHAPTER 5: DIAGNOSIS AND MANAGEMENT OF PRECANCER

5

Chapter 5: Diagnosis and Management of Precancer

Key points

- Further investigations are needed in all women with a positive or abnormal screening test, in order to make a definitive diagnosis.
- The standard method for diagnosis of cervical precancerous lesions is histopathological examination of tissue obtained through biopsy guided by colposcopy.
- The “screen-and-treat” approach involves providing treatment on the basis of a positive screen test, without further diagnostic testing. This is a new approach and the long-term impact on cancer incidence has yet to be evaluated.
- It is essential that precancerous lesions graded CIN 2 or 3 are treated. CIN 1 lesions are more likely to resolve spontaneously, but should be treated if it is likely that the woman will not return for follow-up, and in other special circumstances.
- Outpatient treatments, such as cryotherapy and loop electrosurgical excision procedure (LEEP), are preferable to more invasive treatments (such as cold knife conization), which require anaesthesia and often hospitalization, and have more complications.
- Cold knife conization is appropriate when the eligibility criteria for cryotherapy and LEEP are not met.
- Hysterectomy should not be used to treat precancer, unless there are other compelling reasons to remove the uterus. A desire for surgical sterilization is not an acceptable reason.

ABOUT THIS CHAPTER

This chapter describes diagnostic and treatment procedures for precancer – colposcopy and biopsy, cryotherapy, loop electrosurgical excision procedure and cold knife conization – and discusses their indications, advantages and disadvantages. It also outlines the “screen-and-treat” approach.

ROLE OF THE PROVIDER

The health care provider is responsible for ensuring that all women with abnormal screening tests receive the follow-up and treatment they need. They should explain to women with a positive screening test what follow-up is indicated, managing cases

locally where possible, or referring them to a higher-level facility. They also need to counsel women who undergo diagnostic and treatment procedures on the importance of abstaining from sexual intercourse, or using condoms correctly and consistently, for some time afterwards.

STORY

Maria is a 60-year-old Nicaraguan mother with 12 children, who has been married to the same man for 45 years. The teacher at her literacy class told her about a clinic to be held in her village to test women for cervical cancer, and advised her to attend. At the clinic, she had a Pap smear. When she returned for her test results, she was told she had a HSIL, a condition that needed to be treated because otherwise it could get worse and become cancer. She was referred to the district hospital, where a doctor looked inside her vagina with a colposcope and took a biopsy from the abnormal area. The biopsy confirmed that she had a precancerous lesion and she was treated with cryotherapy. The doctor explained the importance of regular examinations after treatment, as sometimes a few abnormal cells remain and continue to progress towards cancer. But Maria was leaving the country and did not return for many months. When she came back, she was told that the health worker had come to visit her and had left a message that it was very important for her to attend the follow-up visit. She finally attended the clinic 18 months after treatment. The doctor in the hospital repeated the colposcopy, which revealed that there was again a suspicious lesion. The biopsy confirmed a CIN 3 lesion, needing further treatment. Maria was admitted to the hospital for a cold knife conization under anaesthesia; she was operated on early in the morning and discharged the same day. The entire abnormal area was removed, and she has had normal follow-up tests since then.



MANAGEMENT OPTIONS FOR PRECANCER

Standard practice for diagnosis: colposcopy and biopsy

Biopsy performed with the aid of a colposcope is the standard method for diagnosis of cervical precancer and preclinical invasive cancer. For satisfactory biopsy, the entire transformation zone must be visible to allow the degree of abnormality to be assessed and to identify areas for biopsy. If the SCJ or the transformation zone is partially or entirely inside the cervical canal, an endocervical speculum examination should be done to visualize any lesions in their entirety, and an endocervical curettage (ECC) done to obtain a sample for histopathological examination. If precancer is diagnosed, it should be treated using cryotherapy, LEEP or cold knife conization.

Barriers to colposcopy and biopsy services

Ideally, colposcopy and biopsy should be used to manage women with a positive screening test, but there are frequently barriers to the establishment of these services:

- Colposcopes are sophisticated, relatively expensive instruments.
- Specialized training and experience are required to maintain proficiency.
- Biopsy samples need to be transported to a histopathology service, which may be difficult in low-resource settings.

Alternative approaches to diagnosis and treatment

“Screen-and-treat” approach

In this approach, treatment decisions are based on the results of the screening test, without a prior diagnostic test. Most screen-positive women can be treated with cryotherapy at primary health care level at the time of screening; this could reduce loss to follow-up and have an impact on cervical cancer control. However, tissue will not be available for later examination. This approach is discussed in more detail in Annex 4b.



Screen and treat

Colposcopy-based “see-and-treat” approach

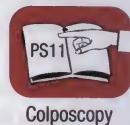
To address the issue of potential overtreatment with the screen-and-treat approach, an intermediate approach can be used. Patients with a positive screen (on Pap smear, VIA, VILI, or HPV) can be examined with a colposcope. If a precancerous lesion is detected, it can be treated immediately. If cryotherapy is the chosen treatment, colposcopically-directed biopsies can be taken before treatment to confirm the diagnosis following the procedure. If LEEP is used, tissue will be available as a result of the procedure. This approach is contingent on the availability of equipment and trained and experienced providers.

DIAGNOSIS

Colposcopy, biopsy and endocervical curettage

Colposcopy

Colposcopy is the examination of the cervix, vagina and vulva with a colposcope, which provides illumination and magnification, allowing the cellular patterns in the epithelial layer and surrounding blood vessels to be examined. Application of dilute acetic acid¹² will highlight abnormal areas, which can then be biopsied. Used as a diagnostic tool on patients with a positive screen test, colposcopy has a high sensitivity (around 85%) and a specificity of about 70% for the detection of precancer and cancer.



Colposcopy is used to:

- visually evaluate precancerous and cancerous lesions;
- help define the extent of lesions;
- guide biopsies of areas that appear abnormal;
- assist treatment with cryotherapy or LEEP.

Colposcopy should not be used as a screening tool.

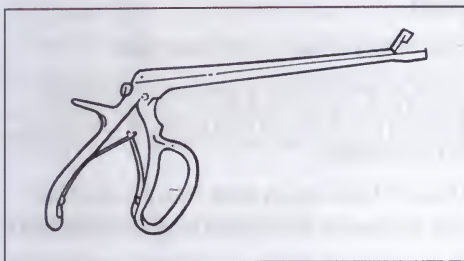
RECOMMENDATION

Colposcopy is recommended only as a diagnostic tool and should be performed by properly trained and skilled providers.

Biopsy

Biopsy is the removal of small areas of the cervix for histopathological diagnosis. It should be done only with colposcopic assistance. With a punch biopsy forceps (Figure 5.1), one or more small pieces of tissue (1–3 mm across) are removed from the abnormal areas of the cervix identified by colposcopy. Bleeding is usually minimal. The samples are placed in a preservative, such as formalin, and the container labelled. This is then sent to a laboratory for precise histopathological diagnosis of the abnormalities, whether they are precancer or cancer, and their severity and extent, so that treatment can be tailored to each case.

¹² Staining with Lugol's iodine, although still used, is not recommended for routine use because it can potentially produce artefacts in the biopsy specimen.

Figure 5.1 Cervical punch biopsy forceps**Endocervical curettage**

If a woman has a positive Pap test, but no abnormal areas are observed with colposcopy, there may be a lesion in the cervical canal. In this case, the endocervix can be examined with a special speculum and a sample of cells can be obtained with an endocervical curette for microscopic diagnosis. Endocervical curettage is a simple procedure, in which some of the surface cells are gently scraped from the cervical canal. The cells are then sent to a laboratory for examination. The procedure takes only a few minutes.

Colposcopy, biopsy and endocervical curettage are almost painless (although they may cause brief cramping) and do not require anaesthesia. After a biopsy or endocervical curettage, the woman should abstain from sexual intercourse until she has no more discharge or bleeding; this usually means a couple of days. If this is not possible, she should use condoms.

Providers

If a colposcope, biopsy forceps and an endocervical curette are available, colposcopy, biopsy and endocervical curettage can be performed at primary care level by trained and skilled physicians, nurses and other health care providers. More commonly, they are performed as outpatient procedures at secondary level (district hospital).

Indications for colposcopy and biopsy

Colposcopy and biopsy should be performed:

- on women with an abnormal screening test;
- if suspicious lesions are seen on the cervix on speculum examination;
- to map abnormalities before cryotherapy or LEEP.

Indications for endocervical curettage

Endocervical curettage should be performed in the following circumstances:

- The patient has a positive Pap smear, but no abnormality is seen with colposcopy. There may be a precancer or cancer hidden inside the cervical canal, which can be detected by examining tissue obtained by curettage.
- The Pap smear revealed a glandular lesion. These usually arise from the columnar epithelium inside the canal. In this case, endocervical curettage must be performed regardless of the colposcopy findings.
- Colposcopy was unsatisfactory because the transformation zone was not seen in its entirety.

Special considerations

- **The entire transformation zone is not visible.** In this case, the colposcopy is unsatisfactory and an endocervical curettage should be done. If this is not possible, women should be referred for LEEP or cold knife conization. This is especially important if the screening test revealed a high-grade lesion.
- **The woman is pregnant.** As discussed in Chapter 4, pregnancy is not the ideal time to perform a screening test. However, if a test is done and is abnormal, or if a lesion is noted on speculum examination, the patient should be referred for colposcopy. Taking biopsies during pregnancy can be associated with significant bleeding. Therefore, if there is no colposcopic indication of invasive cancer, the patient can be given an appointment to return at 12 weeks postpartum for colposcopic re-evaluation and possible biopsy. If cancer is suspected, she should be referred immediately to a specialist.
- **The woman is postmenopausal.** In many postmenopausal women, the entire transformation zone is not visible. If an adequate endocervical curettage is not possible, a cold knife conization should be done.
- **The woman is HIV-positive.** Management of abnormalities, including colposcopy and biopsy, should not be modified on the basis of a woman's HIV status. During the healing process after any procedure, seropositive women might have increased virus shedding and, if re-exposed, might be more likely to acquire an additional virus load. Abstinence from intercourse until healing has occurred is most important.

Follow-up

The patient should be asked to return in 2–3 weeks for the results of the biopsy. Treatment options, according to the severity and extent of the abnormality, should then be discussed with her. Women who do not return as requested should be contacted, given their results and advised about what treatment they need (see Chapter 4 for strategies to ensure that women receive the information they need).

TREATMENT OF PRECANCER

Patient management depends on the results of the colposcopy, biopsy and endocervical curettage, and should be in line with national guidelines. The flowchart in Annex 5 indicates management options.



Flowchart precancer

Principles of treatment

In most cases, precancerous lesions can be treated on an outpatient basis using relatively non-invasive procedures, such as cryotherapy or LEEP. For lesions that cannot be treated in this way, inpatient methods such as cold knife conization can be used. Hysterectomy, a highly invasive procedure with a risk of complications, such as infection, haemorrhage and injury to adjacent organs, should not be used to treat precancer, unless there are other reasons to remove the uterus. Desire for permanent contraception on the part of the patient is *not* an acceptable concurrent reason for hysterectomy.

RECOMMENDATION

Precancer should be treated on an outpatient basis whenever possible. Both cryotherapy and LEEP may be suitable for this purpose, depending on eligibility criteria and available resources.

Indications for treatment

All biopsy-confirmed CIN 2 and 3 lesions should be treated, because the majority of them persist and may eventually progress to invasive cancer. CIN 1 is more likely to resolve spontaneously; these patients can be followed up with colposcopy and cytology every 6 months until the lesion regresses to normal, or there is evidence of progression of the abnormality. If progression is noted, or in cases where follow-up is problematic, as well as in older women in whom spontaneous regression is less likely, immediate treatment should be considered.

Special considerations

- **Pregnancy.** Women known or suspected to be pregnant should not be treated for precancer; they should be advised to return at 12 weeks postpartum for further evaluation. If invasive cancer is suspected, the patient should be referred immediately to a specialist (see Chapter 6).
- **The woman is menstruating.** Women who present for treatment during menstruation can be treated if the bleeding is slight. It is advisable to delay the procedure if menstruation is heavy and interferes with visualization of the extent of the lesion.
- **The woman has a cervical infection or pelvic inflammatory disease (PID).**
 - A cervical infection with no evidence of PID (diagnosed clinically during speculum examination or with laboratory tests) can be treated with antibiotics concurrently with cryotherapy. If LEEP or cold knife conization is to be used, the infection must be treated before the procedure.
 - If PID is suspected, a full course of appropriate antibiotic treatment should be completed prior to any treatment.
 - Whenever a woman is treated for a cervical infection, with or without PID, her partner also needs to be fully treated to prevent reinfection. Until both have been fully treated, they should be advised to abstain from sexual intercourse or use condoms. Condoms and instructions on their use need to be provided to all such patients.
- **The woman is HIV-infected.** HIV-positive women should be managed in the same manner as uninfected women. However, HIV-positive women are known to have higher rates of persistence, progression and recurrence of disease after treatment. Women with HIV infection should therefore be monitored every 6 months after treatment, and promptly re-treated if persistent, progressive or recurrent high-grade lesions are detected.

At present there is no clear evidence on whether treatment with highly active antiretroviral drugs modifies regression or progression of cervical precancer and cancer. Before any treatment, HIV-positive women should receive counselling to ensure that they understand the need for close follow-up, and the possibility of need for repeat treatments, as well as the potential for increased transmission and acquisition of STIs and HIV during healing. Abstinence from sexual intercourse is the best protection following treatment; if this is not feasible, condoms should be used consistently and correctly.

RECOMMENDATION

Women should be offered the same treatment options irrespective of their HIV status.

Treatment methods

Treatment methods may be ablative (destroying abnormal tissues by heating or freezing) or excisional (surgically removing abnormal tissues). The main disadvantage of ablative methods is that, unless a biopsy is taken before treatment, there is no tissue specimen for histological examination and confirmation of the lesion.

The choice of treatment will depend on:

- the training and experience of the provider;
- the cost;
- the advantages and disadvantages of each method;
- the location and extent of the lesion.

Cryotherapy and LEEP are the recommended outpatient treatment options. Cryotherapy is the easiest and least costly treatment method for precancer. However, LEEP is the treatment of choice when the lesion is too large for the cryoprobe or involves the endocervical canal, or when a histological specimen is needed. The two methods have comparable effectiveness (see Table 5.1). Cold knife conization should be done when the eligibility criteria for outpatient methods are not fulfilled, or when such methods are not available.

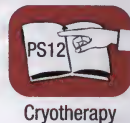
Regardless of the treatment method to be used, the patient must receive full information on what will be done. Informed consent must be obtained before the procedure is undertaken.



Informed consent

Cryotherapy

Cryotherapy eliminates precancerous areas on the cervix by freezing them. This relatively simple procedure takes about 15 minutes and can be performed on an outpatient basis. It involves applying a highly cooled metal disc (cryoprobe) to the cervix, and freezing its surface using carbon dioxide (CO₂) or nitrous oxide (N₂O) gas. The cryoprobe is applied to the cervix twice, for three minutes each time, with a 5-minute thaw in between (double-freeze technique). A continuous supply of carbon dioxide or nitrous oxide is required. The more expensive, bone-dry medical grade of gas is preferred, but industrial-grade gas can be used if that is what is locally available and affordable. Cryotherapy is highly effective for the treatment of small lesions, but for larger lesions the cure rate is below 80%. Because the area of the cervix that is frozen has very few nerve endings, cryosurgery is generally associated only with some cramping or mild pain. It can, therefore, be done without anaesthesia.



Providers

Cryotherapy can be performed at all levels of the health care system by a variety of trained providers (doctors, nurses, midwives) skilled in pelvic examination, and trained in cryotherapy as an outpatient procedure.

Indications and exclusion criteria

Eligibility criteria	Exclusion criteria
• Positive screening test for cervical precancer • Lesion small enough to be covered by the cryoprobe with no more than 2 mm beyond its edges • The lesion and all edges fully visible with no extension into the endocervix or onto the vaginal wall	• Evidence or suspicion of invasive disease or glandular dysplasia • The lesion extends more than 2 mm beyond the cryoprobe edge • Pregnancy • PID (until treated) • Active menstruation

Loop electrosurgical excision procedure (LEEP)

LEEP, also called large loop excision of the transformation zone (LLETZ), is the removal of abnormal areas from the cervix using a thin heated wire. It requires an electrosurgical unit that produces a constant low voltage and transmits it to a wire loop device, which is used to remove the abnormal tissue. The loops are of very fine stainless steel or tungsten wire and come in different sizes and shapes. The loop cuts and coagulates at the same time. LEEP aims to remove both the lesion and the entire transformation zone. The tissue removed can be sent for examination to the histopathology laboratory, allowing the extent of the lesion to be assessed. Thus, LEEP serves a double purpose: it treats the lesion, and at the same time, produces a specimen for pathological examination. The procedure also has the advantage that it can be performed under local anaesthesia on an outpatient basis. It is successful in eradicating precancer in more than 90% of cases. Treatment failure (i.e. persistent lesions at 6 or 12 months follow-up) is seen in less than 10% of women.



LEEP

Providers

LEEP is a relatively simple surgical procedure, but it should be performed only by a well trained provider with demonstrated competence in the procedure and in recognizing and managing intraoperative and postoperative complications, such as haemorrhage. LEEP is best carried out in facilities where back-up is available for management of potential problems. In most resource-poor countries, this will limit LEEP to second-level (district hospital) facilities.

Indications and exclusion criteria

Eligibility criteria	Exclusion criteria
• A positive diagnostic test for precancer • Lesion extending less than 1 cm into the endocervical canal	• Suspicion of invasive cancer or glandular dysplasia • Lesion extending more than 1 cm into the endocervical canal, or whose distal or upper extent is not visible (these lesions are treated by cold knife conization) • Cervical infection or PID (until treated or resolved) • Pregnancy or delivery within the last 12 weeks • Bleeding disorders

Cold knife conization

Cold knife conization is the removal of a cone-shaped area from the cervix, including portions of the outer (ectocervix) and inner cervix (endocervix) (Figure 5.2). Conization is recommended for the treatment of dysplasia when outpatient treatment is not feasible or not accessible, and to rule out invasive cervical cancer. It is a rather extensive operation, involving removal of a large area of the cervix with a scalpel, and is usually done under general or regional (spinal or epidural) anaesthesia. It takes less than one hour. The patient may be discharged from hospital the same or the next day. Because of possible side-effects, cold knife conization should be reserved for cases that cannot be resolved with cryotherapy or LEEP excision. The extent of the conization will depend on the size of the lesion and the likelihood of finding invasive cancer. The woman's desire to have more children also has to be taken into account, as conization may result in cervical stenosis or incompetence in a few women. The tissue removed is sent to the pathology laboratory for histological diagnosis and to ensure that the abnormal tissue has been completely removed.

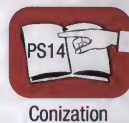
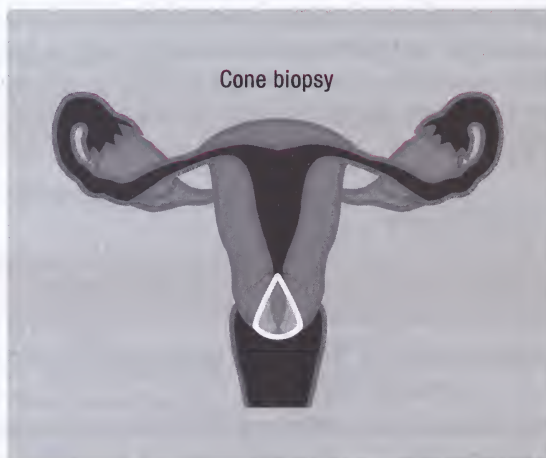


Fig 5.2 Area of the cervix removed in conization



Providers

Cold knife conization should be performed only by providers with surgical skills, in an equipped surgical facility. Providers are usually gynaecologists or surgeons trained to perform the procedure and to recognize and manage complications.

Indications and exclusion criteria

Eligibility criteria	Exclusion criteria
• Screen or diagnostic test suspicious for microinvasive cancer • Endocervical glandular neoplasia • Abnormal endocervical curettage • Positive screen showing need for excisional procedure and outpatient procedures, such as LEEP, are not feasible • No contraindications to anaesthesia	• Untreated cervicitis or PID • Pregnancy or childbirth within the past 12 weeks • Obvious invasive cancer

Management of complications

After cold knife conization, bleeding is the most common complication; it can occur immediately (primary bleeding) or up to 14 days after the procedure (secondary bleeding). In either case, the patient needs to return to the surgical facility. Secondary haemorrhage is usually related to local infection and, along with measures to stop the bleeding, treatment with antibiotics should be prescribed.



Table: 5.1 Comparison of cryotherapy, LEEP and cold knife conization

	Cryotherapy	LEEP	Cold Knife Conization
Advantages	• High cure rate (86–95%) for small lesions • Equipment simple and relatively inexpensive • Can be performed by trained and competent physicians and non-physicians. Training takes a few days • Can be performed as an outpatient procedure in a primary care setting • Fast (about 15 minutes for double-freeze method) • Anaesthesia not required • Electricity not required • Complications and side-effects rare	• High cure rate (91–98%) • Reliable histology specimen obtained, which allows invasive disease to be ruled out • Few complications • Can be performed on an outpatient basis at a secondary level • Fast (5–10 min) and technically simple to perform • In a see-and-treat approach, diagnosis and treatment can be offered at the same time, maximizing treatment coverage	• Highly effective (cure rate 90–94%) • A single surgical specimen, without “burnt” edges, is removed, which facilitates the evaluation of the margins for complete excision of the diseased area
Disadvantages	• Less effective for larger lesions (cure rates < 80% at one year) • No tissue sample available for histological examination • Needs continuous supply of carbon dioxide or nitrous oxide • Causes prolonged and profuse watery discharge	• Requires intensive training • Postoperative bleeding in less than 2% of treated women • More sophisticated equipment needed • Requires electricity • Requires local anaesthesia	• Requires hospitalization and an operating theatre • Requires spinal or general anaesthesia • Requires highly skilled personnel • Complications may occur, including bleeding, infection, stenosis and cervical incompetence with possible decreased fertility

The “screen-and-treat” approach

If there is no capacity for tissue diagnosis with colposcopy and histology, treatment based on screening alone may be appropriate, especially in limited-resource settings. Screening tests for the screen-and-treat approach can include visual tests, HPV or

cytological tests. With screening tests that provide immediate results, such as VIA and VILI, screening and treatment can be provided during a single hospital visit. However, a second visit might be needed in the following circumstances:

- The patient is menstruating heavily, is pregnant or needs treatment for PID.
- The therapy available is not appropriate for the lesion.
- Treatment is not available at the same site and the patient needs to be referred to another facility.
- The client prefers to discuss the treatment with her partner before proceeding.
- The client needs further evaluation.

Studies and pilot projects using the screen-and-treat approach have mainly focused on the use of visual tests for screening and cryotherapy for treatment, because of the advantages of a single-visit approach that can be decentralized to primary care level. A flowchart for this approach is given in Annex 4b. It is important to note that the impact of the screen-and-treat approach on the incidence and mortality of invasive cervical cancer is not yet known. Therefore, if this approach is implemented in countries, careful monitoring and evaluation must be carried out.



Advantages and limitations of the screen-and-treat approach

Advantages	Limitations
• Infrastructure and equipment are simpler and less costly, and provider level lower • Single-visit approach reduces loss to follow-up and treatment, resulting in a reduced burden of tracking and contacting women • Lowers burden for women by reducing the number of visits • Highly acceptable to women and providers	• Impact on cervical cancer incidence and mortality not yet known • Important ethical and resource use concerns, including overtreatment and undertreatment ¹³ • No specimen available for later evaluation, unless biopsy taken before treatment

¹³ Overtreatment is treatment of women who do not have disease. If specificity of VIA is 85%, about 15% of women screened would be treated on the basis of false positive results, wasting resources and increasing exposure to potential risks and side-effects. Undertreatment occurs if women with invasive disease or disease within the endocervical canal are treated with cryotherapy.

FOLLOW-UP AFTER TREATMENT

Women should return for a follow-up visit 2–6 weeks after treatment. The visit should include the following:

- gynaecological examination to ensure the cervix is healing well;
- counselling to emphasize the need for regular follow-up;
- discussion of results of histopathology (in the case of LEEP and conization).

If the entire lesion was removed, the patient should return for further follow-up visits at 6 and 12 months. In cases of positive margins (for precancer) after LEEP or cold knife conization, the patient should be advised that she will need close follow-up and might need further treatment.

Follow-up visits after 6 and 12 months should include the following:

- A screening test and, if possible, colposcopy and directed biopsy of any persistent lesions.
- If no abnormalities are seen on the first two follow-up visits, patients treated for CIN 1 or CIN 2 can be referred back to the screening programme. Patients treated for CIN 3 should be rescreened every year for 5 years, and then referred back to the screening programme (see Annex 5).



Flowchart precancer

- If the lesion progresses or persists, re-treatment is needed.

DIAGNOSIS AND TREATMENT ACTIVITIES AT DIFFERENT LEVELS

In the community



- Support women who have been treated, by encouraging abstinence from intercourse or condom use, helping with removal of vaginal packing, enquiring about and acting on symptoms of complications.
- Provide condoms to all women. Train them in consistent and correct use.
- Contact the health centre if the patient has questions that you cannot answer, or if you are concerned about her status.
- Keep records and visit women to remind them when they have to return to the health centre for follow-up.
- Track women who do not return for follow-up, on request of providers at the health centre.

At the health centre



- Perform colposcopy, biopsy and cryotherapy (if providers have necessary training and equipment).
- Refer women who need further care to the district hospital.
- Provide routine and emergency follow-up care for women treated in the health centre and district hospital.
- Maintain communication with the district hospital and with CHWs.
- Train, supervise, and support CHWs doing home visits, and provide supplies.
- With CHWs, track women who do not return to the centre in a timely manner.

At the district hospital



- Manage women referred by the health centre (for diagnosis and treatment) and advise women on follow-up.
- Refer women with invasive disease and complications requiring higher expertise to the central hospital.
- Assist in the training and supervision of CHWs and health centre staff.
- Maintain two-way communication with health centre staff.

At the central hospital



- Maintain quality services in the histopathology laboratory.
- Manage women who are referred by the lower levels.
- Train and supervise workers at lower levels.
- Maintain communication with lower levels about referred women, their management and follow-up.

Counselling messages

5

For women who will be managed at your level:

- Explain management options.
- Explain procedures that they are likely to need and where they take place.
- Obtain informed consent.
- Explain what follow-up is needed.

For women who are referred to a different level for diagnosis, treatment or complications:

- Explain why you are referring her, and when and where she must go.
- Tell her that she can come to see you if she has questions and concerns.
- Educate her about self-care, and symptoms of complications, and advise her what to do if she experiences any symptoms.

Advise all women to use condoms, train women (and their partners) in how to use them, and provide them with condoms.

ADDITIONAL RESOURCES

- ACCP. *Effectiveness, safety, and acceptability of cryotherapy. A systematic literature review*. Seattle, WA, Alliance for Cervical Cancer Prevention, 2003 (Cervical Cancer Prevention Issues in Depth, No.1).
- McIntosh N, Blumenthal P, Blouse A, eds. *Cervical cancer prevention: guidelines for low-resource settings*. Baltimore, MD, JHPIEGO, 2001.
- Sellors JW, Sankaranarayanan R. *Colposcopy and treatment of cervical intraepithelial neoplasia: a beginners' manual*. Lyon, IARCPress, 2003.
- WHO. *Sexually transmitted and other reproductive tract infections. A guide to essential practice*. Geneva, 2005.
- Wright TC, Richart RM, Ferenczy, A. *Electrosurgery for HPV-related diseases of the lower genital tract. A practical handbook for diagnosis and treatment by loop electrosurgical excision and fulguration procedures*. Quebec, Arthur Vision Inc., 1992.

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PRACTICE SHEET 11: COLPOSCOPY, PUNCH BIOPSY AND ENDOCERVICAL CURETTAGE

PS 11

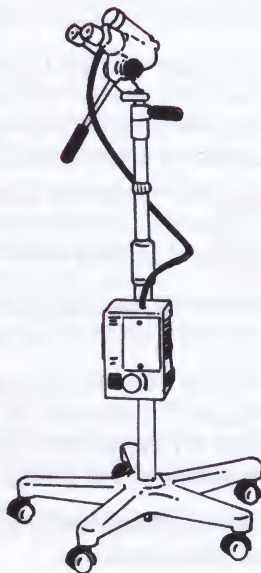
WHAT ARE COLPOSCOPY AND BIOPSY?

Colposcopy is the use of a colposcope (Figure PS11.1) – an instrument that provides magnification and a strong light – to look at the cervix. Biopsy involves taking a small tissue sample from the abnormal areas of the cervix using a biopsy forceps. Biopsy may cause mild discomfort or cramping. An endocervical curettage (ECC) can also be performed to obtain a sample of cells from inside the cervical canal. This can cause cramping, but not severe pain, and occasionally may trigger a vasovagal reaction.¹⁴

The following equipment and supplies are needed for colposcopy, biopsy and ECC:

- vaginal speculum, high-level disinfected, and sterile endocervical speculum;
- normal saline solution;
- 3–5% acetic acid;
- colposcope;
- Monsel's paste;
- punch biopsy forceps;
- endocervical curette;
- ring forceps;
- cotton swabs;
- specimen bottles with 10% formalin;
- pencil and labels.

Figure PS11.1 Colposcope



For basic equipment to perform a pelvic examination refer to PS7.

¹⁴ Occasionally, when an ECC is being performed, the patient may experience a vasovagal reaction, which is usually self-limiting. If it persists, elevate the patient's legs and lower her head.

PERFORMING COLPOSCOPY, BIOPSY AND ECC

Preparation

1. Explain the procedure, what the tests may show, and why it is important to return for further management as requested. Ensure that the patient has understood and obtain informed consent.
2. Show the patient the colposcope and explain how you will use it to examine her.
3. Prepare the patient for a gynaecological examination, and do a speculum examination (see Practice Sheet 7).
4. Make sure the posterior fornix (vaginal space surrounding the ectocervix) is dry.

Procedure

5. Tell the patient what you will do at every step, and warn her before you do anything that might cause cramps or pain.
6. Inspect the cervix at low-power magnification (5x to 10x), looking for any obvious areas of abnormality (e.g. leukoplakia, condylomata). Identify the transformation zone and the original and new squamocolumnar junctions. If advisable, or if the entire SCJ is not visible, you can inspect the cervical canal using an endocervical speculum. If the entire SCJ is still not visible, the colposcopic procedure is termed inadequate or unsatisfactory and an endocervical curettage should be done (see Step 12).
7. Apply saline to the cervix. Inspect the cervix with a green filter and 15x magnification, noting any abnormal vascular patterns.
8. After telling the patient that she might feel a mild stinging sensation, apply acetic acid.¹⁵ Wait one or two minutes to allow colour changes to develop. Observe any changes in the appearance of the cervix. Give special attention to abnormalities close to the SCJ.
9. Integrate the findings of the saline test and the acetic acid test to make a colposcopic assessment.
10. Tell the woman that you will take a biopsy of her cervix, which may cause some cramping.

¹⁵ Sometimes Lugol's iodine is applied after the acetic acid, to help in identifying the lesion. However, it is not always possible in resource-poor settings. Moreover, the routine use of Lugol's iodine is not recommended because high concentrations can cause histological artefacts in the biopsy specimen.

11. Take cervical biopsies of the most abnormal areas, and place tissues in separate labelled bottles containing formalin.
12. If necessary, perform an endocervical curettage. Hold the curette like a pen and scrape the endocervical canal in short firm strokes until it is completely sampled. Keep the curette inside the canal during the entire procedure. At the end, remove the curette, place the curettings on gauze or brown paper, and immediately immerse in 10% formalin.
13. If active bleeding is noted, apply Monsel's paste to the bleeding areas.
14. Withdraw the colposcope and gently remove the speculum.



Monsel's paste

After the procedure

15. Explain what you saw and, if you took biopsies and endocervical curettings, what these may reveal.
16. Advise the woman how to take care of herself when she goes home:
 - a. She should abstain from sexual intercourse until she has no more discharge or bleeding. If this is not possible, she should use condoms.
 - b. She should not insert anything in the vagina for 3 or 4 days.
 - c. Tell her the signs and symptoms of complications: active bleeding, serious cramping or lower abdominal pain, pus-like discharge, fever. If she experiences any of these, she needs to return to the centre or go to hospital.
17. Provide condoms and teach her how to use them.
18. Give a specific date for the return visit. Laboratory reports should be available within 2–3 weeks, so a follow-up visit should be planned 2–3 weeks after the colposcopy.
19. Explain when the results will be available, and the importance of returning to the clinic for them.
20. Document the findings. Use appropriate forms to record the colposcopic assessment.
21. Send labelled biopsies and curetted tissue to the laboratory.
22. If you noted something you cannot handle, refer the woman immediately to a higher level for further examinations or tests.



Condom use

Follow-up (2-3 weeks after the colposcopy)

23. Explain what is in the laboratory report.
24. Advise the patient what follow-up she needs, on the basis of the results. Use national guidelines or, if not available, the flowchart in Annex 5, to advise the woman of her diagnosis and recommended treatment plan.
25. Do a pelvic examination and check for healing.
26. Refer her for needed therapy or make an appointment for the next visit.



Flowchart precancer

Your job is not done until you have reviewed the histopathological report with the patient and have a treatment plan in place.

PRACTICE SHEET 12: CRYOTHERAPY

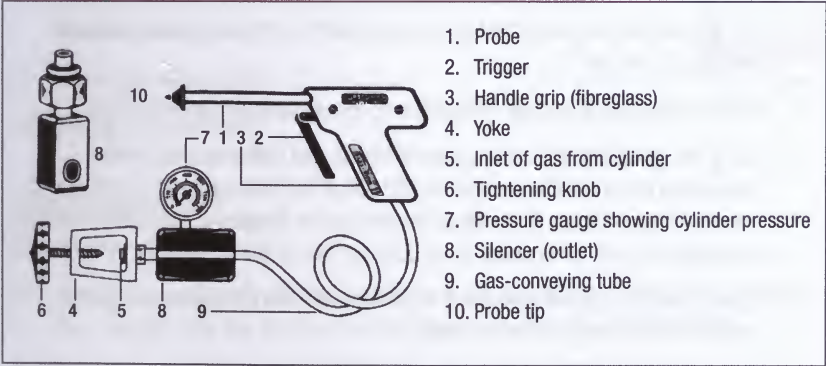
Cryotherapy is the freezing of the abnormal areas of the cervix by the application of a very cold disc to them. It takes only a few minutes and usually only causes some cramping.

The following materials and equipment are needed for cryotherapy:

- speculum, high-level disinfected (it need not be sterile);
- disposable or high-level disinfected examination gloves (need not be sterile);
- cotton swabs for wiping the cervix;
- normal saline solution;
- colposcope, if used in the particular venue;
- cryosurgery unit with adequate gas supply (Figure PS12.1).

For basic equipment to perform a pelvic examination refer to PS7.

Figure PS12.1 Cryotherapy equipment components



Source: Sellors JW, Sankaranarayanan R. *Colposcopy and treatment of cervical intraepithelial neoplasia: a beginners' manual*. Lyon, IARC Press, 2002.

PS12

PERFORMING CRYOTHERAPY**Before the procedure**

1. Explain the procedure, and why it is important to return for further management as requested. Ensure that the woman has understood and obtain informed consent.
2. Show her the cryotherapy equipment and explain how you will use it to freeze the abnormal areas on the cervix.
3. Prepare the patient for a gynaecological examination, and perform a speculum examination (see Practice Sheet 7).
4. If there is no evidence of infection, proceed with cryotherapy.
5. If there is a cervical infection, provide treatment as described in Annex 8. You may proceed with the cryotherapy, or you may give the patient an appointment to return once the infection is cured.



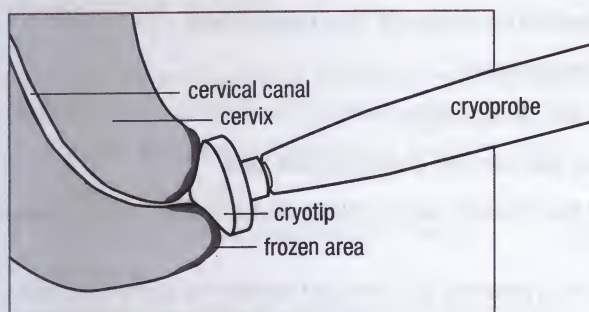
PS6 Informed consent
PS7 Pelvic exam

Procedure

6. Wipe the cervix with a saline-soaked cotton swab and wait a few minutes.
7. Apply acetic acid to outline the abnormality and wait a further few minutes.
8. Tell the woman she might feel some discomfort or cramping while you are freezing the cervix.¹⁶
9. Wipe the cryoprobe surface with saline to ensure optimum effectiveness.
10. Apply the cryoprobe tip in the centre of the os and make sure the probe adequately covers the lesion (Figure PS12.2). If the lesion extends more than 2 mm beyond the probe, discontinue the procedure. Explain to the woman why you are doing this and what needs to be done for her as an alternative.
11. Ensure that the vaginal wall is not in contact with the cryoprobe or you may cause a freezing injury to the vagina.
12. Set the timer and release the gas trigger to cool the probe.
13. You will observe the ice forming on the tip of the cryoprobe and on the cervix (Figure PS12.2). When the frozen area extends 4–5 mm beyond the edge of the cryoprobe, freezing is adequate.

¹⁶ In some cases, the patient may have a vasovagal reaction, with fainting and plummeting blood pressure. If this happens, stop the treatment immediately and raise the patient's legs as much as possible.

Figure PS12.2 Position of cryoprobe on the cervix and ice forming



14. Allow two cycles of freezing and thawing: 3 minutes freezing, followed by 5 minutes thawing, followed by a further 3 minutes freezing.
15. Once the second freezing is complete, allow time for thawing before attempting to remove the probe from the cervix. Removing it before it is fully thawed will pull tissue off the cervix.
16. Gently rotate the probe on the cervix to remove it. The area you have frozen will appear white.
17. Examine the cervix for bleeding. If bleeding is noted, apply Monsel's paste.
18. Do not pack the vagina.
19. Remove the speculum.



Monsel's paste

After the procedure

20. Provide a sanitary pad.
21. Instruct the woman to abstain from intercourse and not to use vaginal tampons for 4 weeks, until the discharge stops completely. This to avoid infection.
22. Provide condoms for use if she cannot abstain from intercourse as instructed. Teach her how to use them.
23. Invite her to return in 2–6 weeks to be checked for healing, and again in 6 months for a repeat Pap smear and possible colposcopy.



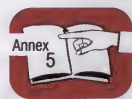
Condom use

PS12

24. Inform her of possible complications and ask her to return immediately if she notes:
 - a. fever with temperature higher than 38 °C or shaking chills;
 - b. severe lower abdominal pain;
 - c. foul-smelling or pus-like discharge;
 - d. bleeding for more than two days or bleeding with clots.
25. Clean and disinfect the cryoprobe and decontaminate the cryogun, tubing, pressure gauge and gas tank:¹⁷
 - a. Decontaminate the cryotherapy unit, hose and regulator by wiping them with alcohol.
 - b. Wash the cryotip and the plastic sleeve with soap and water until visibly clean.
 - c. Rinse the cryotip and plastic sleeve thoroughly with clean water.
 - d. High-level disinfect (HLD) the cryotip and plastic sleeve by one of the following methods:
 - boil in water for 20 minutes; or
 - steam for 20 minutes; or
 - soak in chemical disinfectant (0.1% chlorine solution or 2–4% glutaral) for 20 minutes and then rinse with boiled water.
 - e. It is critical that the hollow part of the cryotip is completely dry when next used, otherwise the water will freeze and the probe could crack or the treatment not work.
 - f. Either use a rubber cap to seal off the hollow part of the cryoprobe during processing, or thoroughly dry the cryoprobe before it is reused.
 - g. If none of the high-level disinfection options are available, the cryotip and sleeve may be disinfected by soaking in 70–90% ethanol or isopropanol for 20 minutes. Allow to air-dry and then reassemble.

Follow-up

26. Perform a pelvic examination to check for healing 2–6 weeks after the cryotherapy.
27. At 6 and 12 months, do a Pap test and a colposcopy and take a biopsy if necessary. Follow up as described in Annex 5.



Flowchart precancer

¹⁷ Some cryoguns get blocked by ice. This can be avoided by pushing the defrost button every 20 seconds to clean the tube. Alternatively, use the cryotherapy gas conditioner developed by PATH.

PRACTICE SHEET 13: LOOP ELECTROSURGICAL EXCISION PROCEDURE (LEEP)

PS 13

LEEP is the removal of abnormal areas from the cervix, using a thin wire heated with electricity. It is successful in curing precancer in 9 out of 10 women.

The following equipment and supplies are needed for LEEP:

- reliable power supply;
- electrosurgical generator and electrode handle;
- colposcope;
- non-conducting speculum, preferably with side retractors;
- return electrode;
- wire electrodes of several sizes (Figure PS13.1);
- coagulating/ball electrode;
- smoke evacuator;
- forceps;
- local anaesthetic: 1% or 2% lidocaine, with or without 1:100 000 epinephrine;
- 5-ml syringes with long 27-gauge needle;
- bottles with normal saline and with 5% acetic acid;
- Monsel's paste;
- large swabs;
- needles and suture material;
- specimen containers with 10% formalin.

For basic equipment to perform a pelvic examination refer to PS7.



Figure PS13.1 Different types and sizes of electrodes

- (a) Ball electrode
- (b) Square loop electrode
- (c) Semicircular loop electrode

PS13

PERFORMING LEEP**Before the procedure**

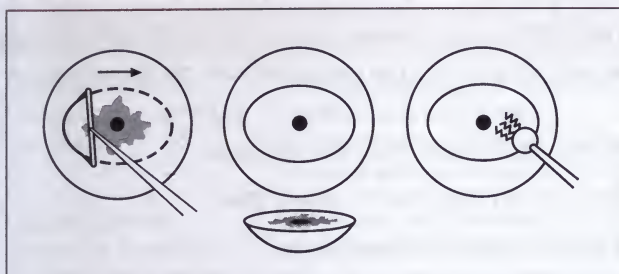
1. Explain the procedure and why it is important to return for further management as requested. Ensure that the woman has understood and obtain informed consent.
2. Prepare the patient for a gynaecological examination.
3. Attach a return electrode to the inner thigh.
4. Insert a non-conducting speculum with an electrically insulating coating, or a speculum covered with a latex condom.
5. Look at the cervix, and note any abnormalities, such as discharge from the os, inflammation, bleeding or lesions. Record the findings.
6. If there is no evidence of infection, proceed. If you note signs of infection, suspend the procedure and treat the patient and her partner completely before making a second attempt.

During LEEP¹⁸

7. Before each step, tell the woman what you will do and what she may feel.
8. Wipe the cervix with a saline-soaked cotton swab.
9. Apply 5% acetic acid and examine with the colposcope to determine the location and extent of the lesion.
10. Inject 3–5 ml of local anaesthetic (1% or 2% lidocaine with 1:100 000 epinephrine (to control bleeding)), using a long 27-gauge needle, just beneath the cervical epithelium at the 12 o'clock, 3 o'clock, 6 o'clock and 9 o'clock positions (in patients with cardiac problems, use lidocaine without epinephrine).
11. Select the appropriate electrode to remove the entire abnormal area in a single pass: for small low-grade lesions in nulliparous women, use an electrode 1.5 cm wide by 0.5 cm deep; for larger lesions and multiparous women, use one 2.0 cm wide by 0.8 cm deep.
12. Turn the vacuum suction on and activate the generator.
13. Excise the lesion: push the electrode perpendicularly into the tissue to a depth of 4–5 mm and draw it laterally across the cervix to the other side, producing a dome-shaped circle of tissue with the canal in the centre. *Do not* insert the electrode deeper than 5 mm at the 3 o'clock and 9 o'clock positions, because this can damage the uterine arteries.

¹⁸ In some cases, the patient may have a vasovagal reaction, with fainting and plummeting blood pressure. If this happens, stop the treatment immediately and raise the patient's legs as much as possible.

Figure PS13.2 LEEP of an ectocervical lesion with one pass: excision of the lesion with wire electrode and fulguration with ball electrode



14. Additional passes with the loop can be made to excise residual tissue.
15. Pick up all excised tissues with the forceps, and place in a labelled bottle with formalin to send to the histopathology laboratory.
16. Perform an endocervical curettage and place the tissue in a separate bottle with formalin.
17. Fulgurate any bleeding tissue in the crater base using a ball electrode and coagulation current.
18. Apply Monsel's paste to the crater base to prevent further bleeding and remove the speculum.



Monsel's paste

After the procedure

19. Provide a sanitary pad.
20. Instruct the patient to abstain from sexual intercourse for a minimum of 4 weeks, and until the bleeding stops completely. This to avoid infection and heavy bleeding.
21. Provide condoms for use if she cannot abstain as instructed. Teach her how to use them.



Condom use

PS13

22. Tell her she may have some mild to moderate pain for a couple of days; she can take ibuprofen or paracetamol.
23. Explain that she may have very light bleeding and that she will notice blood-tinged discharge for one month or more. She can use sanitary pads but not tampons for this.
24. Advise her how to take care of herself when she goes home:
 - a. She should rest and avoid heavy work for several days.
 - b. She should not put anything in the vagina.
25. Inform her of possible complications and ask her to return immediately if she notes:
 - a. fever with temperature higher than 38 °C or shaking chills;
 - b. severe lower abdominal pain;
 - c. foul-smelling or pus-like discharge;
 - d. heavy bleeding or bleeding with clots.
26. Answer her questions.
27. Recommend that she should return to the health centre in 2–6 weeks to be checked for healing and to receive the laboratory report.
28. Agree a follow-up date with her.

Management of complications of LEEP

Problem	Treatment
Bleeding during the procedure: can be diffuse or arterial	For diffuse bleeding: use a combination of pressure and coagulation with ball electrode. For arterial bleeding: place ball electrode in firm contact with the source and use coagulation current.
Bleeding after the procedure (happens in less than 2% of cases)	Remove blood clot, clean with 5% acetic acid, identify bleeding area, anaesthetize with lidocaine and epinephrine. If bleeding is not heavy, apply Monsel's paste. If bleeding is heavy, fulgurate using either a 5-mm ball electrode or a macroneedle electrode and the coagulation current.
Infection after the procedure: pus-like discharge, pain, fever	Treat with antibiotics: for example, • cefixime 400 mg, orally, single dose, plus • doxycycline 100 mg orally twice a day for 14 days, plus • metronidazole 400–500 mg, orally, twice daily for 14 days

At the first follow-up visit (2–6 weeks)

29. Ask how she is feeling and if she has had any unexpected problems since the LEEP.
30. Review the pathology report and advise next steps based on it.
31. Examine her to check healing.
32. Make an appointment for the next visit.

At 6 months and 12 months

33. Do a Pap test and a colposcopy, and take a biopsy if necessary. Follow up as described in Annex 5.



Flowchart precancer

PS13

Practice Sheet 13: Loop Electrosurgical Excision Procedure (LEEP)

PRACTICE SHEET 14: COLD KNIFE CONIZATION

PS 14

Practice Sheet 14: Cold Knife Conization

Cold knife conization is the surgical removal of a cone-shaped area of the cervix. It should be done by a specialist, and the patient should be given anaesthesia or sedation. This Practice Sheet is included to allow a first- or second-level health care provider to explain to a patient, before she goes to hospital, how the procedure will be performed, and to help her recover once she returns home.

EXPLAINING THE PROCEDURE

Give the woman as much information as you can on the procedure, the anaesthesia, and the possible side-effects and complications of surgery. The description below will help you answer any questions she may have.

Before the woman goes to hospital

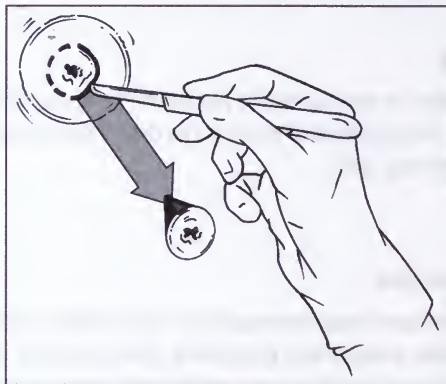
1. The hospital staff will give her instructions for preparation: what clothing to take with her and any medicines she needs to take beforehand. She will be told not to eat or drink anything in the 8 hours before surgery, and to bathe before going to hospital.

The operation

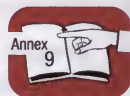
2. General or regional anaesthesia will be used for the operation.
3. The surgeon will insert a speculum to visualize the cervix.
4. An iodine solution will be applied to highlight the abnormal areas, and the cervix will be examined with a colposcope.
5. A substance to reduce risk of heavy bleeding will be injected into the cervix. Or the surgeon may suture the small arteries supplying the area to be removed.

6. A cone-shaped area of the cervix, including the endocervical canal, will be removed using a special knife (Figure PS14.1). The removed tissue will be placed in a jar with formalin and sent to the laboratory, with the findings recorded on the appropriate histology form.

Figure PS14.1 Removal of a cone-shaped area of the cervix



7. After the cone is removed, the base of the crater (the area of the cervix after excision) will be cauterized using ball cautery.
8. Any active bleeding will be stemmed by applying pressure using cotton balls, and by applying Monsel's paste or by cauterizing using ball cautery.
9. A gauze pack may be placed in the vagina to apply pressure and control the bleeding, but this will not be done if Monsel's paste has been used.



Monsel's paste

Just after the operation

10. After the operation, the patient will be monitored by the hospital staff in the recovery room. Once she wakes up, she will be moved to a regular bed to recover fully.
11. If she feels well, has no significant bleeding, and lives near the hospital, she will be discharged after a few hours. If she is not able to go home the same day, she will be discharged the next day, provided there are no complications.
12. The woman and her partner will be instructed to abstain from sexual intercourse for 6 weeks after the operation, so that the raw area of the cervix has a chance to heal.

At the first follow-up visit (2–6 weeks)

13. A speculum examination will be done to determine if the wound has fully healed.
14. The laboratory results will be discussed and the next steps planned.
15. The patient will be advised to return in 6 months and 12 months for assessment.

At 6 months and 12 months

16. A Pap test and colposcopy will be done, and a biopsy if necessary. The patient will then be followed up as described in Annex 5.



Flowchart precancer

FOLLOW-UP AT HOME

Before she leaves hospital, the woman will be given counselling on how to take care of herself, and what symptoms of complications to look for. You can help her by reinforcing this advice.

1. If gauze packing was left in the vagina, it must be removed within 6–12 hours to avoid infection. If there is a local health care provider who knows how to do this, he or she can assist the woman.
2. Relative rest for a few days is recommended. The patient should avoid heavy work for the first three weeks. Normal daily activities can be performed, such as light housework, bathing, showering, and eating.
3. If the patient has discomfort (not severe pain), she may take paracetamol.
4. She will have a hidden wound in the vagina, which needs at least 4–6 weeks to heal. To prevent infection and allow proper healing, she should not put anything into the vagina for that time, including fingers or tampons, and she should not douche or have sexual intercourse (although she can be intimate in other ways). If she is unable to abstain from intercourse, provide condoms and teach her (and her partner) how to use them.
5. Make sure she knows the symptoms of complications (see next page) and instruct her to go to the health centre or hospital immediately if any of them occur.
6. She should have been given an appointment for a check-up in 2–6 weeks to discuss the results of the tissue examination and to be examined by the surgeon. Encourage her to keep this appointment.

Complication	Symptoms	Treatment
Infection	Pain in the lower abdomen Foul-smelling yellow discharge from vagina	• Provide treatment for PID
Haemorrhage	Heavy vaginal bleeding	• Speculum examination, remove blood clot, identify bleeding areas • Fulgurate/cauterize bleeding area using ball electrode • Apply Monsel's paste or pack with ribbon gauze



Infection treatment

6

CHAPTER 6: MANAGEMENT OF INVASIVE CANCER

CHAPTER 6: MANAGEMENT OF INVASIVE CANCER

Key points

- Health care providers at all levels should know the common symptoms and signs of cervical cancer. If a woman presents with such symptoms, her cervix should be examined visually to determine whether further testing is needed.
- The stage of the cancer is a measure of how far it has advanced. This determines how it can be treated, and the likely outcome.
- Invasive cervical cancer should be treated by specialists at central-level facilities.
- Treatment is by surgery or radiation therapy, with or without chemotherapy.
- Access to treatment greatly improves prognosis and survival rates.
- Curative treatment is possible for all except the most advanced disease.
- The availability of a basic radiotherapy unit (teletherapy and brachytherapy) can permit effective treatment and palliation in all cases of invasive cancer.
- Specialists who diagnose or treat women with cervical cancer should write clear referral letters back to the provider closest to the home of the patient.
- Patients should be made aware that they will need long-term follow-up and contact with the cancer unit where they have received treatment. Providers should facilitate this.

ABOUT THIS CHAPTER

It is important for the welfare and survival of women with invasive cancer that they are managed by specialists at tertiary-level facilities. This chapter describes how cancers are staged (to determine the extent of the disease) and gives the recommended specific management for each stage of disease. It also describes the roles of the specialists involved in care of the patient.

THE ROLE OF THE PROVIDER

The provider at first or second health care levels may have diagnosed invasive cancer in the patient and referred her to a tertiary-level facility. This provider is responsible for making a link between the tertiary care level (where the patient undergoes staging and treatment for invasive cancer) and the patient herself, her family and her community. This chapter is not primarily intended to be used by tertiary-level providers, but rather to help first- and second-level providers to understand how cervical cancer is managed, to explain it to the patient and her family, and to communicate with carers at tertiary and community levels. In addition, the providers will be responsible for identifying and managing side-effects and complications of treatment, and referring the patient back to the treatment facility when necessary.

STORY



Betty, aged 42, has 5 children. For the past 3 months, she has had vaginal spotting and copious bleeding after intercourse. She and her partner were told by the community worker that they should go to the gynaecology department of a specialist hospital as soon as possible. At the hospital, the intern examined her and noted a large fungating mass at the top of the vagina, from which he took a biopsy; he also ordered a haemoglobin test. Because cancer was a high probability, Betty was kept in for the combined assessment clinic

the next day, when she was again examined by a number of doctors, who explained that there was a tumour on the cervix. After examining her, they agreed that the tumour had spread beyond the cervix but that she could be cured. They asked about urinary symptoms, but she had none. An ultrasound scan of the kidneys and ureters was done to see if there was obstruction of urine outflow and these tests were normal, so she was told the cancer was in stage IIB. They offered her treatment with radiotherapy and reassured her that she had a good chance of being cured. However, her periods would stop, she would develop hot flushes and she would not be able to become pregnant again. She and her partner were also informed that women who are treated with radiation may develop discomfort on sexual intercourse, but they would be able to give her advice if it happened. They also explained clearly how the treatment would be applied. Because her blood tests showed that she was anaemic, she first received a blood transfusion. She then received 5 weeks of daily treatment by teletherapy and, from the third week on, treatment by high-dose-rate brachytherapy until 4 applications had been given. The treatment was given on an outpatient basis, so that she could continue to care for her children. However, near the end of the treatment, she felt very tired, so she was admitted to the hospital for a few days. Her partner and older children helped with household duties, not only when she was in the hospital, but also in the weeks after, until she recovered.

DIAGNOSIS

Symptoms and signs of invasive cancer

Microinvasive cancers may be asymptomatic, and may be detected only on investigation of an abnormal Pap smear. On the other hand, most cases of frankly invasive cervical cancer come to the attention of providers and are diagnosed once they become symptomatic (see Table 6.1). If the woman is not sexually active, the disease may remain asymptomatic until it is well advanced. The clinical presentation is determined by the patterns of growth and spread as explained in Chapter 2. Eliciting patients' symptoms is important for optimal patient management and for pain control.

Early detection of cervical cancer

Women may present with one or more of the following complaints: irregular bleeding, postcoital bleeding, postmenopausal bleeding, persistent vaginal discharge (especially when unresponsive to STI syndromic management). They should have a speculum examination to visualize the cervix, and any visible lesions should be biopsied. If the woman is pregnant, she should be referred to a specialist for biopsy and follow-up.

Table 6.1. Symptoms of invasive cancer

Early	• Vaginal discharge, sometimes foul-smelling • Irregular bleeding (of any pattern) in women of reproductive age • Postcoital spotting or bleeding in women of any age, even young women • Postmenopausal spotting or bleeding • In the case of abnormal perimenopausal bleeding, cervical cancer should always be considered, particularly if the bleeding fails to respond to appropriate treatment
Late	• Urinary frequency and urgency • Backache • Lower abdominal pain
Very late	• Severe back pain • Weight loss • Decreased urine output (from obstruction of the ureters, or renal failure) • Leakage of urine or faeces through the vagina (due to fistulae) • Swelling of the lower limbs • Breathlessness (due to anaemia or, rarely, lung metastases or effusion)

The definitive diagnosis of cancer is confirmed by histopathological examination of a tissue specimen taken from the lesion and is mandatory before any therapy, or even extensive investigations, are started.

CERVICAL CANCER STAGING

The purpose of staging

Once a histological diagnosis of cervical cancer has been made, the next step is to formulate the most effective therapy for the individual concerned. In order to manage a cervical cancer patient properly, it is essential to understand the extent or "stage" of her disease at the time of diagnosis. Although staging systems are to some extent artificial, they guide the clinician in both tailoring treatment and assessing prognosis.

Cancer staging systems

A number of staging systems are used for cancer. The classification of the International Federation of Gynecology and Obstetrics (FIGO), which is based on tumour size and the extent of spread of disease in the pelvis and distant organs, is recommended for staging invasive cervical cancer. The extent of growth of the cancer is assessed clinically,¹⁹ supplemented by a limited number of relatively unsophisticated investigations (see Table 6.2). An exception to the above is staging of microinvasive cervical cancers, which are staged according to pathological criteria of the depth and width of the invasive lesion in relation to the epithelium of origin (which may be either squamous or glandular epithelium).

Table 6.2 Investigations for staging and treatment for cervical cancer according to FIGO

Mandatory for staging	Supplementary for staging	Optional, to inform additional treatment, not for staging
• Speculum, vaginal and rectal examination • Intravenous pyelogram (IVP) or • Abdominal ultrasound	• Cystoscopy • Proctoscopy • Cone biopsy • Endocervical curettage or smear • Chest X-ray • Skeletal X-ray or bone scan (if bone pain)	• Blood tests for HIV and syphilis, and haemogram • Computerized tomographic (CT) scan of abdomen and pelvis • Magnetic resonance imaging (MRI) of pelvis

¹⁹ Note: Occasionally a hysterectomy is performed for a reason unrelated to cervical disease and there is an incidental finding of cervical cancer. These cases cannot be clinically staged, but should be treated according to the characteristics reported by the pathologist.

In many low-resource settings, speculum, vaginal and rectal examinations are the only feasible approaches to staging; these will often provide sufficient information when performed by experienced clinicians, who pay particular attention to the size of the tumour and possible involvement of the vaginal fornices, the parametria (transverse cervical and uterosacral ligaments), the pelvic walls, the bladder and the rectum. This assessment can be done under general anaesthesia, if there is any doubt about the diagnosis or if the patient is too tense or in pain. Other imaging modalities, such as computerized tomographic (CT) scan and magnetic resonance imaging (MRI) of the abdomen and pelvis, are optional and not needed for diagnostic and staging purposes. If easily available, they may be used to acquire more detailed information on the extent of the disease and its prognosis, and to inform the choice of treatment. All investigations for the purpose of staging and their results should be carefully documented in the case record. A descriptive diagram should be included whenever an invasive cervical cancer is assessed.

Overview of FIGO stages related to management and prognosis

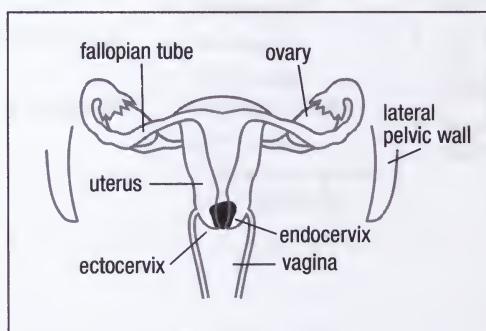
Stage 0: Carcinoma in situ, cervical intraepithelial neoplasia Grade III.

This is not considered invasive cancer, since the lesion has not gone beyond the basement membrane.

Stage I: Carcinoma confined to the cervix. Extension to the uterus is disregarded.

- **IA:** Microinvasive carcinoma, strictly confined to the cervix. Can only be diagnosed by microscopy; it is not clinically visible.
 - **Stage IA1:** Stromal invasion no greater than 3.0 mm in depth and not more than 7.0 mm in horizontal spread.
5-year survival with optimal treatment: ~98%.
 - **Stage IA2:** Stromal invasion of more than 3.0 mm but not more than 5.0 mm in depth and with horizontal spread of 7.0 mm or less.
5-year survival with optimal treatment: ~95%.
- **IB:** Carcinoma strictly confined to the cervix and clinically visible; or a microscopic lesion greater than IA2 (Figure 6.1).
 - **IB1:** Clinically visible lesion 4.0 cm or less in greatest dimension.
5-year survival with optimal treatment: ~85%.
 - **IB2:** Clinically visible lesion more than 4.0 cm in greatest dimension.
5-year survival with optimal treatment: ~75%.

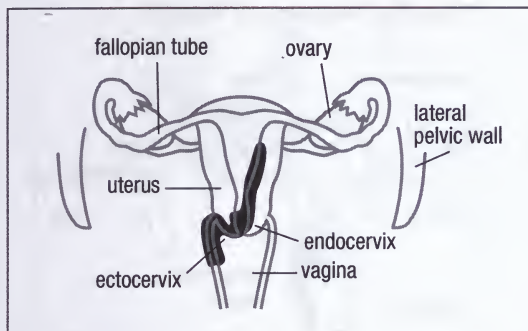
Figure 6.1 Cervical cancer stage IB



Stage II: Carcinoma confined to the cervix. Extension to the uterus is disregarded.

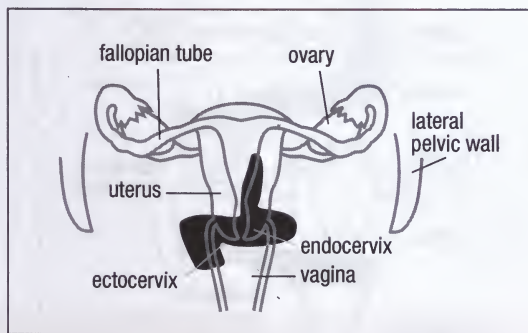
- **IIA:** Spread beyond the cervix, including upper two-thirds of the vagina, but not to tissues around the uterus (parametria) (Figure 6.2).
5-year survival with optimal treatment: ~75%.

Figure 6.2 Cervical cancer stage IIA



- **IIB:** Spread beyond the cervix, with parametrial invasion, but not as far as the pelvic wall or the lower third of the vagina (Figure 6.3).
5-year survival with optimal treatment: ~65%.

Figure 6.3 Cervical cancer stage IIB

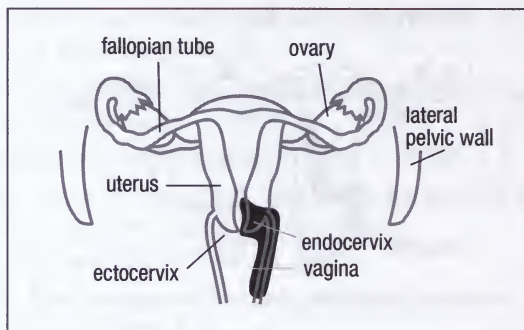


Stage III: Tumour extends to pelvic wall or involves lower third of the vagina, or causes hydronephrosis or non-functioning kidney.

- **IIIA:** Invasion of the lower third of the vagina, with no extension to the pelvic wall (Figure 6.4).

5-year survival with optimal treatment: ~30%.

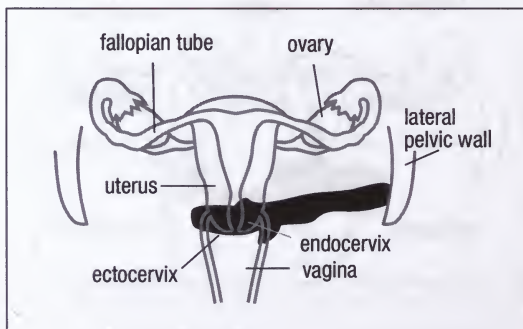
Figure 6.4 Cervical cancer stage IIIA



- **IIIB:** Extension to the pelvic wall, or hydronephrosis or nonfunctioning kidney (Figure 6.5).

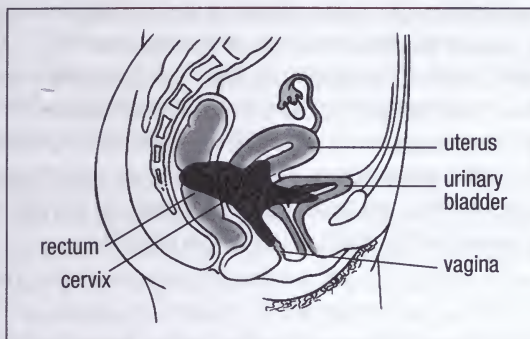
5-year survival with optimal treatment: ~30%.

Figure 6.5 Cervical cancer stage IIIB

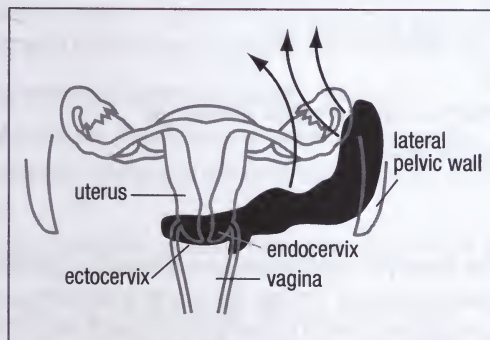


Stage IV: Tumour has spread

- **IVA:** Spread to involve the mucosa of the bladder or rectum (Figure 6.6).
5-year survival with optimal treatment: ~10%.

Figure 6.6 Cervical cancer stage IVA

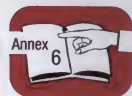
- **IVB:** Spread to distant organs, such as extrapelvic lymph nodes, kidneys, bones, lungs, liver and brain (Figure 6.7).
5-year survival with optimal treatment: <5%.

Figure 6.7 Cervical cancer stage IVB**RECOMMENDATION**

Histological confirmation of cervical cancer and FIGO staging must be completed before embarking on further investigations and treatment.

PRINCIPLES OF TREATMENT

Treatment must be tailored to the best interests of the patient. While the guidelines on optimal clinical management protocols given in Annex 6 should generally be adhered to, overall assessment of the patient, and differences in availability and quality of surgery, radiotherapy and medical oncology services, may affect the treatment offered. Invasive cancer should be treated at tertiary referral centres, where the necessary expertise and equipment are available. Additional tests, including those to determine the patient's suitability to undergo anaesthesia or major surgery, may be required and may affect treatment selection. In HIV-positive women, the CD4 count may also influence the choice of treatment. Testing for syphilis, and blood tests for haemoglobin and liver and kidney function, must also be done before management can be planned.



Management cancer

Survival rates

The survival rate is expressed as the proportion of women surviving 5 years after receiving treatment. It is determined by both disease stage and treatment given. In countries where therapy is either unavailable or inadequate, survival rates are significantly lower than the optimum.

The following factors influence prognosis:

- the clinical stage of disease at presentation: this is the single most important predictor of long-term survival, along with access to treatment;
- age: survival declines with advancing age;
- lymph node status;
- general health, nutritional status, presence of anaemia;
- degree of immunosuppression.

Primary therapy

Primary therapy may be surgery or radiotherapy, or occasionally a combination of both. Chemotherapy is not used for primary therapy, but may be given concurrently with radiotherapy. Curative surgery in cervical cancer aims to remove the primary tumour, with all extensions, in a single operation. The operation undertaken will depend on the clinical stage of the tumour and the findings of the surgeon when the operation is in progress.

RECOMMENDATION

Surgery and radiotherapy are the only recommended primary treatment modalities for cervical cancer.

Explaining procedures and obtaining informed consent for treatment

The provider should adapt the explanations found in this chapter and in the practice sheets to individual situations, in order to explain procedures, such as surgery and radiotherapy, in terms the patient and her family can understand. The general rules for counselling given in Practice Sheet 4 also apply to communication of complex information about treatment. It may be helpful to draw or use pictures to illustrate difficult points. The provider should keep medical terminology to a minimum and explain any technical words that have no local translation.



Women should be given all the information they need about a procedure before it is performed. This should include the possible benefits, risks, potential side-effects and what to do if one or more occur, recovery time, cost, and chance of success. If a woman would like family members to help her make a decision on care, they should be included in the discussion. Providers should follow local and national regulations on obtaining informed consent, as well as hospital regulations regarding the need for a signature or thumbprint on a consent form. At the very least, what was said, who was present, and the woman's understanding and consent, if given, should be documented in her medical record.

Treatment by stage

Of all cervical cancer patients presenting at multidisciplinary gynaecological assessment clinics in tertiary hospitals in developing countries, only about 5% have microinvasive or early invasive cancer (tumours up to stage IB1/IIA <4 cm in diameter).

These cases are preferably treated with surgery because:

- The surgical procedure and recovery in hospital takes less than 2 weeks.
- The extension of the tumour and completeness of removal can be assessed immediately.
- Ovarian function is retained, which is particularly important for premenopausal patients.
- The patient keeps a functional, elastic, and lubricated vagina.
- Most complications are seen within a few days of the procedure.

Surgery should also be favoured for patients with pelvic inflammatory disease, especially when there is an abscess in or near the uterus (pyometra). Radiotherapy, while having the same high 5-year survival rates as surgery, takes about 6 weeks to

administer, and the total extent of the tumour cannot be evaluated. Sequelae, such as loss of vaginal elasticity (fibrosis), shortening and narrowing (stenosis) and dryness of the vagina, may occur months to years after radiation and may make intercourse painful.

About 80% of all cases are in stage IB2 to stage IIIB, with cervical tumours and parametrial involvement extending towards or up to the pelvic side walls, with or without obstruction of the ureters. These bulky tumours, which may measure 10 cm across; have a cure rate ranging from 30% to 75% when treated with radical radiotherapy. Large stage IIA tumours (4 cm or more in diameter) are treated as stage IB2 tumours.

Stage IV tumours are less commonly seen. Stage IVA, with rectal or, less commonly, bladder invasion, accounts for about 10% of cases. Only about 10% of these can be cured, and fistulae between the involved organs and the vagina are frequent. Stage IVB (5% of cases), with distant haematogenous metastases, is incurable by any currently known means. However, effective palliative care can be given in these cases.

If the cancer recurs, it is usually in the two years following treatment. The treatment of recurrent cancer is determined by the extent of disease at recurrence, the disease-free interval, the general condition of the patient, and the primary treatment given.

TREATMENT MODALITIES

Surgery

Curative surgery in cervical cancer aims to remove the primary tumour, with all its extensions, in a single operation. The operation undertaken will depend on the clinical stage of the tumour and the findings of the surgeon when the operation is in progress. Palliative surgery is usually used to relieve distressing symptoms when radiotherapy has failed or caused complications, such as rectovaginal or vesicovaginal fistulae.

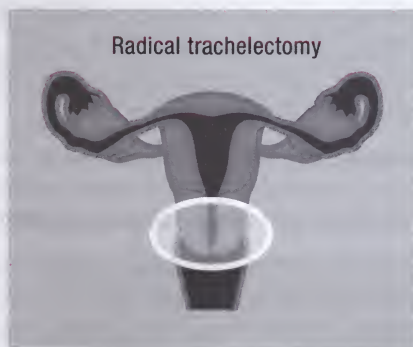
Surgical procedures

The main surgical procedures are radical hysterectomy and pelvic lymphadenectomy, although simple hysterectomy and trachelectomy are indicated in specific cases. After surgery, the patient is usually discharged from the hospital after 7–10 days, but it may take from 6 to 12 weeks for full recovery.

Trachelectomy

Trachelectomy is the removal of the cervix. Radical trachelectomy includes removal of the parametria and upper vagina in addition to the cervix (Figure 6.8).

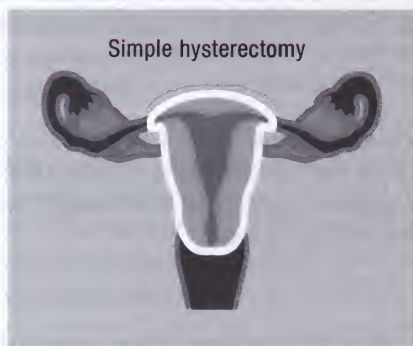
Figure 6.8 Tissue removed by radical trachelectomy



Simple hysterectomy

Simple hysterectomy is the surgical removal of the entire uterus, including the cervix, either through an incision in the lower abdomen, or through the vagina (Figure 6.9). The tubes and ovaries are not routinely removed, but they may be, if they appear abnormal.

Figure 6.9 Removal of the uterus by simple hysterectomy

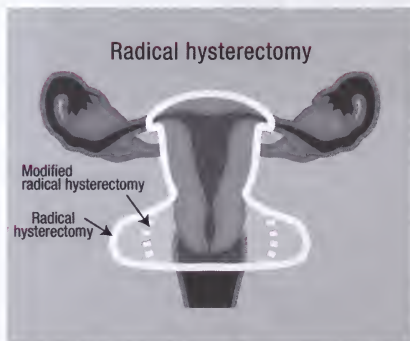


Radical hysterectomy

Radical hysterectomy is the surgical removal of the uterus, cervix, and surrounding tissues (parametria), including 2 cm of the upper vagina (Figure 6.10). The removal of as much cancer-free tissue from around the tumour as possible is associated with a much better cure rate. Ovaries are not routinely removed because cervical cancer rarely spreads to the ovaries. In a modified radical hysterectomy, less parametrium is removed than in standard radical hysterectomy (Figure 6.10).

Recovery time is slightly longer than after simple hysterectomy.

Figure 6.10 Radical and modified radical hysterectomy



It is important to note that, even once the surgery has started, the surgeon may abandon the procedure. This happens when, before incising the peritoneum, the surgeon notices that there is extensive involvement of pelvic nodes. In this case, the patient should be treated with radiotherapy. The peritoneum needs to remain intact, because incising the peritoneum when lymph nodes are involved increases the rate of complications associated with radiotherapy. The procedure for, and complications of, simple and radical hysterectomy are detailed in Practice Sheet 15.



Bilateral pelvic lymphadenectomy or nodal dissection

This operation involves the removal of the three groups of lymph nodes in the pelvis, which are often involved in invasive cervical cancer, even in early stages (IA2 onwards). These nodes are located close to the large blood vessels of the pelvis.

Indications

The specific surgical treatment will depend on the extent of the disease.

Trachelectomy is not a standard procedure, but can be offered to women with microinvasive cancer, who wish to have children in the future. There is increasing evidence that a radical trachelectomy with pelvic lymphadenectomy is a valid procedure for treatment of stage IA2.

Simple hysterectomy is indicated for women with microinvasive cervical cancer of stage IA1 and sometimes IA2. Stage IA2 can be treated with a simple hysterectomy and lymph node dissection, but a modified radical hysterectomy with lymph node dissection is preferred. Hysterectomy is not usually indicated for treatment of high-grade precancerous lesions and carcinoma in situ, which can be treated with simpler outpatient methods, but may be appropriate when there are also other gynaecological problems, such as abnormal uterine bleeding. A desire for sterilization on the part of the patient should not be a reason for hysterectomy.

Radical hysterectomy is performed on women who have invasive cervical cancer, with tumours of up to 4 cm in diameter confined to the cervix, or with very early extension to the vaginal fornices (stages IB1 and IIA). Stage IB1 may not be visible (occult IB1).

Type of provider and level of service

Simple hysterectomy can be performed in a regional or central hospital, by a general or gynaecological surgeon specialized in the treatment of cervical cancer. The operation is performed with general anaesthesia and takes about 2 hours.

Radical hysterectomy is usually performed in a central hospital by a gynaecological surgeon specialized in the treatment of cervical cancer, using general anaesthesia; it takes about 3 hours.

RECOMMENDATION

Surgery for treatment of cervical cancer should be performed only by surgeons with focused training in gynaecological cancer surgery.

Radiotherapy

Radiotherapy plays a central role in the treatment of most invasive cervical cancers. It is mainly used for cases with bulkier tumours (stages IB and IIA through to IVB) and those with extensive involvement of the lymph nodes seen on laparotomy (without hysterectomy). It is also used to manage cancers in patients who are unable to tolerate general anaesthesia. In addition to its curative role, radiation can also alleviate symptoms, especially bone pain and vaginal bleeding.

How radiotherapy works

Notwithstanding its long history of use, radiotherapy is still often poorly understood by the general public. In radiotherapy, the tumour is treated with ionizing radiation. Radiation is like a ray of light with higher energy, which is released as the ray penetrates the body, damaging and destroying cancer cells. It also has a smaller effect on rapidly dividing normal cells in the skin, bladder and large bowel, which causes some of the reversible symptoms noted during and immediately after treatment. The person receiving radiotherapy feels no pain at the time it is being given.

Types of radiotherapy

There are two broad groups of radiation treatment, which differ in terms of position of the source of radiation relative to the patient:

- teletherapy, in which the source of radiation is distant from the patient;
- brachytherapy, in which small radioactive sources are placed in cavities within the body.

Curative treatments are based on a combination of pelvic teletherapy and intravaginal brachytherapy. The procedures and possible complications are described in Practice Sheets 16 and 17.

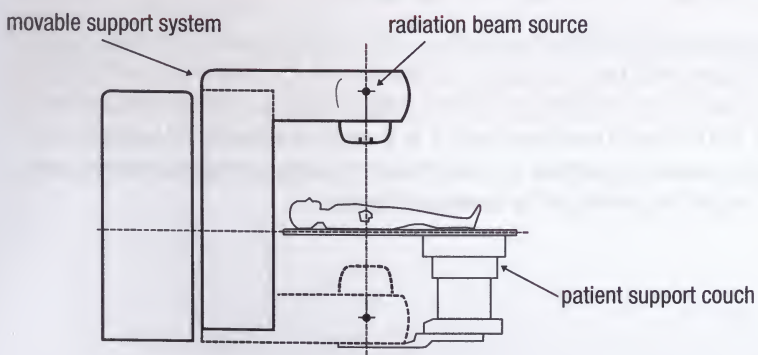


PS16 Teletherapy
PS 17 Brachytherapy

Teletherapy

Teletherapy is also called external beam radiation therapy (EBRT). The origin of the radiation is a shielded head, which has a small opening through which a beam of radiation can pass (Figure 6.11). The beam is aimed at the area of the cervix with cancer and the sites at risk of disease spread. Care must be taken to avoid the bladder and rectum, to protect their function. The treatment is administered in a specialist hospital, and takes place in an enclosed space (therapy bunker). No anaesthesia is needed because the patient feels no pain. Radiation machines weigh many tonnes, and the head can rotate around the treatment table where the patient lies. The head may contain radioactive material, such as cobalt 60, or be a linear accelerator, which accelerates electrons to immense speeds until they hit a target and release their energy as radiation – the same process as a diagnostic X-ray machine. In cervical cancer, the radiation is delivered evenly to the entire pelvic contents, in daily sessions of a few minutes each. Usually four beams are used to deliver the total daily dose. Sessions are given on five days a week for about five weeks. In preparation for this treatment, an image of the pelvis is taken by simulation or computerized tomographic scanning. A computer is then used to plan the treatment. The direction of the beams is verified during the treatment using X-rays.

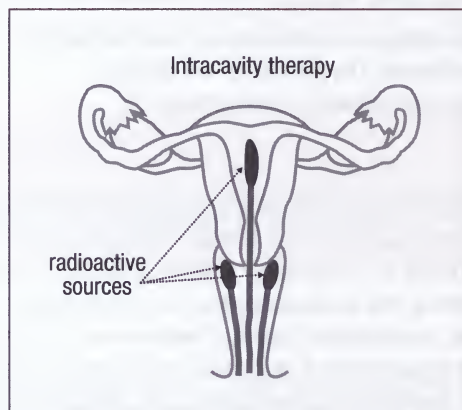
Figure 6.11 Application of teletherapy



Brachytherapy

In brachytherapy, the radiation source is in close contact with the tumour. The radiation sources are placed inside an applicator in the uterus and vaginal vault (intracavity brachytherapy, Figure 6.12).

Fig 6.12 Application of intracavity brachytherapy



The radiation is directed to the cancer on the cervix, uterus, upper vagina and tissue surrounding the cervix (parametria). Care is needed to avoid exposing the bladder and rectum to the radiation, in order to preserve their function as much as possible. The treatment is given by a team of a radiation oncologist, a medical physicist and a radiation technician in a specialist hospital with the appropriate equipment. The radiation is highest within the applicator and decreases rapidly over a few centimetres distance. The dose rate is the speed of delivery of a radiation dose at a specified point. Intracavity brachytherapy can be administered with a low dose rate (LDR), pulsed dose rate (PDR), medium dose rate (MDR) or high dose rate (HDR). The rate used determines the time the patient will be kept in isolation, as well as the total dose to be used, and the number of sessions the patient will have.

The most commonly available brachytherapy devices are LDR and HDR, which have similar effectiveness. Usually, only one of these forms is available in any institution. The two devices are very different in terms of the need for anaesthesia, time spent in hospital, and number of insertions (Table 6.4). It would be advisable for health workers who will be counselling patients on brachytherapy to attend a treatment session at the referral hospital to understand the sequence of events.

Table 6.4: Differences between low-dose-rate and high-dose-rate brachytherapy

	Low dose rate	High dose rate
Commencement	At completion of teletherapy	From the third week of teletherapy
Hospitalization	Inpatient: 2–3 days	Outpatient: 1/2 to 2 hours
Anaesthesia used at placement	General anaesthesia	Mild sedation
Applications	Usually once only	From 2 to 8: usually 4

Indications

Teletherapy is indicated when the entire area affected by the cancer cannot be removed by simple or radical hysterectomy. This means that most women with invasive cervical cancer without distant metastases (stages IB to IVA) should be treated with teletherapy. Brachytherapy is usually used in addition to teletherapy. Its use is mandatory if the intent is to cure cervical cancer. For stages IB1 or lower, if surgery is not possible, brachytherapy can be used as the exclusive treatment.

Provider

Radiotherapy is conducted by a radiation oncologist and a radiotherapy technician with standard radiotherapy training.

RECOMMENDATION

Brachytherapy is a mandatory component of curative radiotherapy of cervical cancer.

Chemotherapy

Chemotherapy is not a primary mode of treatment for cervical cancer, but it may be used concurrently with surgery or radiation to treat bulky tumours. Cisplatin is the most commonly used drug and is included in WHO's Model List of Essential Medicines. The benefits of adding cisplatin to radiotherapy in developing country settings has not been proven. Cisplatin increases the toxicity of radiotherapy and may not be well tolerated by patients with poor nutrition, anaemia, impaired renal function or more advanced cancers. Radiotherapy alone is an acceptable option.

PATIENT FOLLOW-UP

Women who have been treated for cervical cancer should be followed up at the treatment centre, if this is at all possible. The discharge from hospital and follow-up should be discussed at a meeting of all those who have been involved in the patient's care, and should include input from the woman herself and her family. If follow-up needs to be done at a distance from the treatment centre, a primary care physician (preferably a gynaecologist) should receive a comprehensive report detailing the stage, treatment administered, prognosis and common problems expected. The report should include contact information (phone, fax, email, address) of the treatment centre and request regular feedback. The primary care physician should be encouraged to seek advice if the patient presents with unexpected symptoms. Mobile telephones are increasingly available to maintain contact between treating physicians and the patient or family.

Follow-up for women treated with surgery alone

Women who have been treated with surgery alone should have three-monthly follow-up consultations for a period of 2 years, with careful recording of symptoms, particularly bleeding, discharge or pelvic pain.

During the consultations, the following examinations should be performed:

- speculum examination and visualization of the vaginal vault;
- cytological smear of the vaginal vault and of any abnormality noted on examination;
- bimanual vaginal and rectal examination to palpate for recurrence of disease;
- other investigations depending on the clinical findings and resources available.

Recurrent disease in these women can be treated with radiation.

Follow-up for women treated with radiation

For women who have been treated primarily with radiation, follow-up should be the same as for those who have had surgery, but the role of vaginal cytology is less clear and clinical evaluation is more difficult because of radiation-induced fibrosis. One of the reasons for regular follow-up is to look for sequelae of radiotherapy, which may be mistaken for recurrence of cancer. Treatment options for women with recurrence after primary radiation are somewhat limited, as no further radiation can be given. Salvage hysterectomy may be considered where surgical expertise and facilities exist; this approach is unlikely to alter the survival rate, but is associated with a longer disease-free interval and possibly a better quality of life. Chemotherapy is also an option in case of recurrence after radiation. Finally, radiation can be used to treat non-pelvic or distant metastases, e.g. in the bones, lung or other organs.

SPECIAL SITUATIONS

Pregnancy

Although rare, cancer of the cervix is sometimes diagnosed in a pregnant woman. This can pose a serious dilemma for the woman, especially if she is early in her pregnancy. Each case should be treated individually, taking into account the concerns and health of the mother and the impact of possible treatments on the viability of the fetus. The management of cervical cancer in pregnancy is stage-related, as for non-pregnant patients. It is also related to the stage of the pregnancy. A diagnosis of cancer in pregnancy, particularly if it will require termination of the pregnancy, might be difficult for the woman to accept. Skilled counselling will be needed to help the woman and her family come to terms with the diagnosis and arrive at a decision about care. If radiotherapy is used, the treatment begins with pelvic irradiation, which will cause fetal death and abortion. An ultrasound scan must be done to verify that the fetus is no longer viable. After the uterus is evacuated, treatment continues in the usual way. In the third trimester, definitive treatment is usually delayed until the fetus is mature. Then, the baby is delivered by Caesarean section, followed immediately by surgery or radiation as determined by the tumour stage. If radiation is the management of choice, it must be done after involution of the uterus. The overall guidelines for management of invasive cancer in pregnancy are given in Annex 6E.



Annex 6E

HIV/AIDS

A special group of women are those who suffer immunosuppression secondary to infection with HIV. Women with low CD4 counts ($<200 \text{ mm}^3$) are at particular risk of complications when treated by any means. Surgery is preferable when appropriate, and treatment with radiation or chemotherapy must be tailored to the individual.

TALKING TO PATIENTS WHO HAVE INVASIVE DISEASE AND TO THEIR FAMILIES

Disclosure of information

In giving information to women and their families about cervical cancer, it should initially be emphasized that cervical cancer is a treatable disease. A diagnosis of cancer is generally not expected by the woman and her family, and receiving bad news (especially if the cancer is advanced) is never easy. The provider should give such information to the patient, and to her family if the woman wishes, and away from other patients. Some guidelines for disclosure and discussion with families are as follows.

- Respect the culture, norms and customs of the patient; it may or may not be acceptable, for example, to give difficult news directly to her.
- Be clear and direct in meaning and words; do not use words the patient will not understand, or which are vague, such as “growth” or “neoplasm”.
- Do not confuse the patient by saying too much, but do not leave important issues untouched.
- Allow some time for those present to take in the impact of what you have said; then give them time to ask questions.
- As people are often shocked when they receive sudden bad news, they may not fully hear or understand what has been said. Try to talk to the patient and her family (if she agrees) again the next day.
- After the initial diagnosis the patient may go through different stages of denial, anger, and resignation, which require understanding and support.

When further treatment is not feasible

When it becomes obvious that no further anticancer treatment can be given, it is best to counsel the patient and family in a sensitive but truthful manner. Try to avoid saying “nothing more can be done,” because carers can help by relieving symptoms, supplying medication, arranging lower-level care, or just being available. For a patient who has been in hospital and is going home, this is the time to ensure that contact is made with local carers who can provide palliative care services. Questions about how much time is left should be answered honestly, i.e. that one does not know but it may be a question of a few days/weeks/months. This will give an indication to the patient and family of what to expect, so that they can make appropriate arrangements.

Ensuring pain control

When a patient with late-stage cancer goes home, the treating physicians (radiotherapist, oncologist, or gynaecologist) should make sure that she has prescriptions for appropriate pain medications, and that a supply will be available once she leaves the hospital. Most cancer patients, particularly in developing countries, suffer unnecessarily with severe pain without adequate relief, because of restricted availability of opiates at peripheral or lower levels; hospital-based providers, however, may be able to secure and supply the necessary medicines for their patients. There is no substitute for oral morphine for severe pain, though palliative radiotherapy can be a valuable adjunct to morphine for pain relief (see also Chapter 7 and Practice Sheet 18).



Pain management

MANAGEMENT OF INVASIVE CANCER: ACTIVITIES AT DIFFERENT LEVELS

In the community



- Maintain regular direct communication with the patient and her family.
- Maintain regular telephone or personal communication about the patient's condition with health centre staff.
- Detect new distressing symptoms of the disease or side-effects of treatment and inform health centre staff about these findings.
- Provide palliative care as specified in national guidelines and prescribed by specialists and other health care providers.
- Establish links between the patient and her family and faith-based or other assistance agencies, which may provide additional non-medical support.
- Aid the patient and family during the terminal stages as much as possible.

At the health centre



- Maintain oversight of the patient's condition and communication with community-based health workers and with district and tertiary health care staff.
- Provide follow-up, as advised by treating facility, if appropriate at this level or if patient is unable to go to higher-level facilities.
- Prescribe and administer treatment for side-effects of treatments received or symptoms of disease in consultation with the treating centre.
- If feasible, do home visits for severely ill and terminal patients who cannot come to the centre.
- Collaborate in training of community workers and staff newly integrated into care team.

At the district hospital



and

At the central hospital



- Provide treatment.
- If it is not possible to manage the patient directly, inform lower-care levels of needed follow-up and medical care to be provided, including prescription of medicines for pain relief.
- Maintain communication with patient's family and carers by telephone, mail, etc.
- Collaborate in training of lower-level providers in care of cancer patients.

Counselling messages

Make sure you address the following issues with the patient and family:

- the stage of her cancer;
- the treatment she received before discharge;
- what possible side-effects she may note and how to deal with them;
- the symptoms of complications and where she needs to go if she experiences any of them;
- needed follow-up: when, where, who to see;
- your willingness to be supportive in any way possible.

ADDITIONAL RESOURCES

- Benedet JL, Bender H, Jones H III, Ngan HY, Pecorelli S. FIGO staging classifications and clinical practice guidelines in the management of gynaecologic cancers. FIGO Committee on Gynecologic Oncology. *International Journal of Gynecology and Obstetrics*, 2000, 70(2): 209-262.
- Chao KSC, Perez CA, Brady LW, eds. *Radiation oncology: management decisions*, 2nd ed. Philadelphia, PA, Lippincott, Williams & Wilkins, 2001.
- Fletcher GH, ed. *Textbook of radiotherapy*, 3rd ed. Philadelphia, PA, Lea and Febiger, 1980.

PRACTICE SHEET 15: HYSTERECTOMY

PS 15

Hysterectomy is the removal of the uterus. In simple hysterectomy, the entire uterus, including the cervix is removed. The tubes and ovaries may or may not be removed. In radical hysterectomy, the uterus plus tissues around it and part of the upper vagina are removed. The overall procedures are essentially identical. This Practice Sheet is included to allow a first- or second-level health care provider to explain to a patient, before she goes to hospital, how the procedure will be performed, and to help her recover once she returns home.

EXPLAINING THE PROCEDURE

Give the woman as much information as you can on the procedure, the anaesthesia, and the possible side-effects and complications of surgery. The description below will help you answer any questions she may have.

Before the woman goes to hospital

1. The hospital staff will give her instructions for preparation: what clothing to take with her and any medicines she needs to take beforehand. She will be told not to eat or drink anything in the 8 hours before surgery, and to bathe before going to hospital.

In the hospital, preparation for surgery

2. The details of the operation will be explained and informed consent obtained.
3. To help prevent infection, the woman's genital and abdominal areas will be cleaned with soap, water and iodine; her genital hair may be clipped.
4. General anaesthesia will be given intravenously or by inhalation.
5. A plastic tube (catheter) will be placed into her bladder and her urine will be collected in a bag.
6. A gauze pack will be placed in her vagina to make it easier for the surgeon to remove tissues around the cervix.

PS15

The operation

7. A cut will be made in the lower abdomen, vertically or horizontally.
8. In *simple hysterectomy*, the uterus is cut away from where it is attached to the fallopian tubes and the vagina. In *radical hysterectomy*, the surgeon removes the uterus, parametria, cervix and the top two centimetres of the vagina. After the uterus and parametria are removed, the surgeon will remove three sets of lymph nodes from the fatty tissue around the large blood vessels of the pelvis.
9. All the tissues removed will be placed in a preservative solution and sent to the laboratory, where a pathologist will examine them to determine if the entire cancer has been removed.
10. At the end of the operation, a drain may be left in the pelvis; this is a plastic tube placed in the abdomen to drain blood and fluid into a bag. It may be left in place for 24–48 hours.
11. Most surgeons will also put a tube (known as a suprapubic catheter) from the outside of the abdomen into the bladder, to drain urine. It will be left in place for 5–7 days in case the nerves to the bladder have been damaged.
12. The abdomen will then be sewn closed and wiped clean, and the wound bandaged.

Just after the operation

13. After the operation, the patient will be cared for by hospital staff in a special recovery room. Once she wakes up, she will be moved to a regular bed to recover.
14. When the patient wakes up, she will have drips and tubes coming out of her body; she will also have nausea, which will last for a few hours. For the first few days, she will have pain in the abdomen where the operation was done. The hospital staff will give her medicines to relieve the pain and nausea for as long as she needs them.

Recovery in the hospital

15. In the hospital, the staff will make sure that the patient regularly coughs and breathes deeply, sits up, moves her muscles, and walks as soon as she is able. This helps to prevent complications.

16. All the moving around of tissues and organs in the pelvis during the operation can damage some of the nerves that supply the bladder and the rectum. As a result, both organs may become “lazy” afterwards, i.e. they empty less efficiently than before the operation. Passing urine or stool will be difficult. The suprapubic catheter will be left in place for a few days, until she can urinate normally again. In most cases the bladder and rectum will have partially recovered before the patient is discharged from the hospital, and they will return completely to normal within 3–6 months of the operation.
17. Most hospitals will allow the patient to return home after 7–10 days, depending on how fast she recovers and what care is available at home. Complete recovery from a radical hysterectomy takes 6–12 weeks.

Follow-up (6 weeks after surgery)

18. The woman will be given the results of the microscopic examination of the tissue removed. The surgeon will examine her thoroughly to make sure that she is recovering normally. Any problems detected will be managed.
19. She will be examined with a speculum to make sure the wound in the vagina has healed.
20. The information from the laboratory will allow the surgeon to discuss with her how far the cancer had spread, what other treatment might be needed, and the chances of the cancer returning.

FOLLOW-UP AT HOME

Before she leaves hospital, the woman will be given counselling on how to take care of herself, and what symptoms of complications to look for. You can help her by reinforcing this advice.

1. To help the patient to recover from the operation, other members of the family should take over her normal household tasks for the first 3–6 weeks, until she regains her strength. During these weeks, the woman should avoid doing heavy housework, walking long distances, carrying heavy objects, or performing other physically taxing tasks. She can perform normal daily activities, such as bathing, showering, and eating normally. She should take short walks a couple of times a day, as she gradually regains strength and returns to normal.
2. The family should encourage the patient to rest when she seems tired, and make sure she eats well.

PS15

3. The woman will have a hidden wound in the vagina, which needs at least 6 weeks to heal. To prevent infection and allow proper healing, she should not put anything into the vagina for that time, including fingers or tampons, and she should not use vaginal douching or have sexual intercourse (although she can be intimate in other ways). Her partner's support in this will be important.
4. The chart below lists some symptoms that may occur in the few weeks after surgery, and what the woman should do if they occur.

If she feels	Cause	What she should do
Depression – feeling sad after a major operation is common	Pain, fatigue, worry	Wait; this should not last more than 2 weeks or so
Abdominal discomfort – this is normal	Soreness from the cutting that was done	Eat food high in fibre, drink plenty of liquids, take stool softeners (bisacodyl); this should disappear within 6 months
Difficult and slow urination; bladder not emptying properly	Nerve damage during surgery, “lazy” bladder	“Double void”: pass urine normally then get up, walk around for a few minutes and pass urine again. If this does not work, she may have to put a tube in herself. The hospital will show her how to do this and give her the materials. The problem should disappear within 3– 6 months
Tiredness – this is normal	The body is healing itself and needs extra rest	Lie down to rest during the day as often as she needs

5. Make sure that the patient and her family know the signs and symptoms of complications (see below) and instruct her to go to the health centre or hospital if any of them occur.

Complication	Signs and symptoms
Infection of the abdominal wound	Pain, redness and pus in the cut area on the abdomen
Infection in the pelvis	Pain (not just discomfort) in lower abdomen, often with fever, foul-smelling vaginal discharge or bleeding
Lymphocyst – caused by collection of lymph fluid after removal of lymph glands	Swelling or pain in the lower abdomen 2–3 months after surgery
Bladder infection	Burning sensation on urination; frequent urination
Blood clot in the leg (thrombosis)	Redness, pain and swelling in one leg

Supplies needed at home: these can be obtained from the hospital or a prescription written for later if needed:

- paracetamol for mild pain (if needed);
- stool softener (e.g. bisacodyl);
- urinary catheters;
- gauze bandage and disinfectant for wound.

PS15

Practice Sheet 15: Hysterectomy

PRACTICE SHEET 16: PELVIC TELETHERAPY

Pelvic teletherapy is radiation given to the pelvic area from a distance, using a special machine (Figure PS16.1).

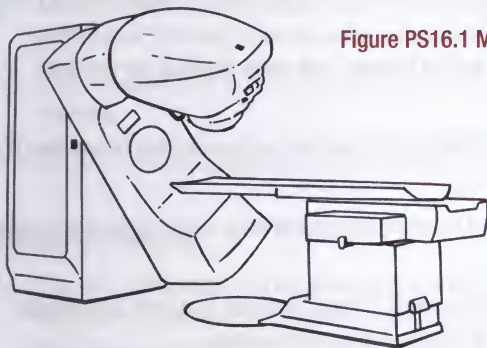


Figure PS16.1 Machine for teletherapy

This Practice Sheet is included to allow a first-or second-level health care provider to explain to a patient, before she goes to hospital, how the procedure will be performed, and to help her recover once she returns home.

EXPLAINING THE PROCEDURE

Give the woman as much information as you can on the procedure, and the possible side-effects. Tell her what the treatment will consist of and who will be in charge of it at the hospital. Tell her that she will be alone during treatment, but that it will not take long and that it does not hurt. The description below will help you answer any questions she may have.

Before the therapy starts

1. The hospital staff will give her instructions for preparation: what clothing to take with her and any medicines she needs to take beforehand.
2. The details of the treatment, its possible complications and options will be explained and informed consent requested. The woman will receive an appointment for pelvic imaging (with X-rays) on a simulator or computerized tomographic (CT) scanner.

PS16

Preparation for treatment

3. On the first day at the hospital, she will be asked to undress and to lie on a special table. She may have a pelvic examination, and X-rays will be taken. With the information obtained from the X-rays, her abdomen and pelvis will be marked with an indelible pen. This is to help the operator limit the radiation to the tumour; she must not rub these marks off.
4. She will be told the schedule for the therapy, and when to return for the first treatment.
5. The patient will be given the following information and counselling concerning the entire period of the therapy:
 - To avoid potential chafing of the skin, she should wear loose clothing and avoid wearing trousers.
 - She can shower with warm water, but should not soak in a bath, and should avoid sponging, rubbing the skin and using harsh soaps.
 - She should not put anything into the vagina during the entire therapy (such as tampons), or have sexual intercourse (although she can be intimate in other ways).
 - She should avoid commercially available skin creams, as they may contain harmful heavy metals. If she needs to use cream, she should ask the staff at the health centre to prescribe it for her.
 - She should cut down on heavy work and work performed in a hot, sweaty environment.
 - She can continue with her usual housework or light office work.
 - She may experience some tiredness or depression near the end of the course of treatment, and she should limit her activities accordingly.
 - The repetitive daily treatments will become boring. She should keep in mind that the chance of cure is diminished if she misses appointments or breaks her schedule, thus delaying completion of therapy.

Treatment

6. On the first day of treatment, the radiotherapy technician will reconfirm the patient's identity, therapy plan and informed consent. The technician will explain the procedure and show her the therapy machine inside the bunker.

7. The patient will be placed on the therapy table and told to remain in position. All personnel will leave the room.
8. She will be alone inside the treatment room, but she will have closed circuit television and audio links for communication.
9. During treatment, the therapy machine will be moved several times automatically, or the technician will enter the room to move it.
10. The patient will not feel anything during the therapy, which lasts only a few minutes.
11. Usually, 25 such treatments will take place over a period of 5 weeks.

Repeat treatments

12. The daily treatments will be as described above. The patient will be encouraged to report any problems to the technician. If it is felt she needs a more specialized response, she will be referred to the radiation oncologist.

Side-effect	Signs and symptoms	What to do
Skin response to radiation	Redness starting after about 3 weeks and increasing with treatment. Possibly dry then moist peeling of the skin, especially in the fold between the buttocks.	Only gentle occasional washing of the area. Avoid scrubbing. If painful, take mild analgesia. If the reaction is severe (usually because of excessive washing) the radiation oncologist may delay the completion of treatment (this can compromise the cure rate).
Bowel effects	The rectum and terminal colon, which reabsorb water from the bowel contents, are in the pelvic region. Radiation may impair water reabsorption, resulting in loose stools or diarrhoea.	The radiation oncologist will prescribe medication if required. Usual household remedies should not be used.
Bladder effects	Urinary frequency and urgency. There may be a burning sensation on passing urine. Rarely there may be evidence of blood in the urine.	Patient should return to the hospital for examination and treatment.

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13. The radiation oncologist will see the patient once a week for a "treatment check", and will ask about any signs or symptoms and assess how well the patient is tolerating treatment.
14. The woman will be informed about common acute side-effects of radiotherapy (see below) and what to do if they occur. These side-effects will resolve spontaneously once the treatment is finished.

Follow-up

15. The patient will be given an appointment to return 6 weeks after completion of the teletherapy. The doctor will examine her and check the vagina to determine if it has healed.
16. The oncology team (radiation oncologist and gynaecologist) is best placed to assess any symptoms related to the pelvic area – in the vagina, bowel and bladder. They should be told about any symptoms or signs that appear to be unusual or severe.

WHAT YOU CAN DO DURING AND AFTER THE THERAPY

1. Help the woman to keep a positive attitude.
2. Counsel her and her husband that she should not have sexual intercourse during the treatment period. After this period, it is recommended that the woman remains sexually active.
3. Inform her that she does not need to use contraception. Pregnancy is impossible during and after teletherapy to the pelvis.
4. Ask her to keep the regular follow-up appointments with the team of radiation oncologist and gynaecologist. If she has unusual or severe symptoms, she should make an earlier appointment than scheduled.
5. Tell the family that they should help the woman to recover from the therapy by doing her normal household tasks for her, until she regains her strength.
6. Encourage her to lie down during the day if she feels tired; make sure she eats well.

7. Inform the woman about late complications:

- The radiation will cause a premenopausal woman to enter the menopause, with its typical symptoms of lack of menstruation, hot flushes, and vaginal dryness.
- The vaginal symptoms of menopause are made worse by vaginal fibrosis and narrowing of the vaginal tube, making intercourse uncomfortable or impossible. Vaginal lubricants and dilators should be prescribed to keep the vagina free of adhesions. It is important to keep the vagina open to allow inspection of the cervix. Continued sexual activity should be encouraged.
- Starting 6 months after treatment, the skin exposed to radiation may show areas of pigmentation, depigmentation or stiffening.
- Long-term narrowing of the rectum, and a passage (fistula) between the vagina and the rectum may develop. These are very disabling complications, which may need further surgery or even a colostomy.
- The bladder may become stiff and reduced in size, causing the woman to urinate frequently, and predisposing her to urinary infections. Rarely, a vesicovaginal passage or fistula develops, resulting in incontinence. This may require surgical repair.
- Very rarely (one patient in a thousand), the radiation may stimulate the development of a new cancer.

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Practice Sheet 16: Pelvic Teletherapy

PRACTICE SHEET 17: BRACHYTHERAPY

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Brachytherapy is radiation therapy delivered from a source of radiation placed close to the tumour, i.e. inside the uterus and in the vaginal vault. This Practice Sheet is included to allow a first-or second-level health care provider to explain to a patient, before she goes to hospital, how the procedure will be performed, and to help her recover once she returns home.

EXPLAINING THE PROCEDURE

Give the woman as much information as you can on the procedure, the anaesthesia, and the possible side-effects and complications of the therapy. The description below will help you answer any questions she may have.

Low-dose-rate (LDR) brachytherapy

Preparation

1. The hospital staff will give her instructions for preparation: what clothing to take with her and any medicines she needs to take beforehand.
2. The details of the treatment and its possible complications will be explained, and informed consent requested. The patient will receive an appointment for admission to hospital.

Procedure

3. On the day of the procedure, the patient will be taken to the operating room and given a general anaesthetic.
4. She will have a tube placed in her bladder.
5. A pelvic examination will be performed.
6. Through a speculum in the vagina, special metal devices will be placed into the cervical canal and around it in the vagina. These devices will hold the radioactive sources.
7. Their position will be checked with X-rays.
8. When she wakes up, she will be taken to an isolation ward (shielded room).
9. She will be instructed to remain on her back in bed for the duration of the treatment (about 2 days).
10. The urinary catheter will remain in place and will be attached to a bag to collect urine.

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11. The hospital staff will leave the room and the radioactive sources will be loaded under computer control into the metal devices previously inserted close to the tumour.
12. The patient will not feel any pain at all while she is receiving the treatment.
13. During the entire procedure, the door of the room will remain closed. She will need to use a bedpan to empty her bowel. The patient will be able to communicate with the nursing staff by audio link, and all meals will be served in bed. She can spend the time reading, listening to radio, or watching television. But she must remain in bed for the entire time! Very limited visiting will be permitted.
14. When the time for the procedure has been completed, she will be given a mild sedative and the devices containing the radiation sources will be removed.
15. Once she has recovered from the sedation, she will be discharged from the hospital.

In some hospitals, two such treatments are given with a one-week interval between them.

High-dose-rate (HDR) brachytherapy

The procedure is similar to that for LDR brachytherapy, with the following differences:

1. Treatment will usually start in the third week after starting teletherapy.
2. Each treatment lasts only one hour, and is given on an outpatient basis. It can be performed under mild analgesia; anaesthesia is seldom used.
3. After catheterization, repeat manual and speculum vaginal examinations will be performed and vaginal retractors and speculum inserted.
4. A metal brachytherapy catheter is inserted into the uterus, and attached to the remote afterloading HDR brachytherapy unit that contains the radioactive source.
5. The patient will be told to remain in position while the personnel leave the room. She must remain in the same position for the whole time that she is receiving radiation, which takes several minutes.
6. She can be discharged when the procedure is over.
7. The number of treatments varies from 2 to 8, but is usually 4. The interval between treatments may vary from one day to a week.
8. After the first treatment, the patient will be given a series of appointments for the rest of the treatments.

Possible side-effects and complications of gynaecological brachytherapy

The side-effects of brachytherapy are the same as those of pelvic teletherapy (see Practice Sheet 16). The information and counselling to be provided to the patient are also similar. Inform the patient about the anaesthesia or sedation she will receive to make her feel more comfortable. Brachytherapy makes a major contribution to vaginal symptoms of local fibrosis, mucosal atrophy and formation of petechiae, which predisposes to local bleeding. It also contributes to late rectal and bladder complications.



Pelvic teletherapy

PS17

Practice Sheet 17: Brachytherapy

7

CHAPTER 7: PALLIATIVE CARE

CHAPTER 7: PALLIATIVE CARE

Key points

- Palliative care is an essential element of cervical cancer control.
- The goal of palliative care is to avoid unnecessary suffering and improve the quality of life of women with advanced cervical cancer and their families, through emotional support, symptom control, end-of-life care and bereavement care. It addresses the physical, psychosocial, and spiritual needs of patients and their families.
- Palliative care should begin as soon as cervical cancer is diagnosed, so that needs can be anticipated, and preventive and treatment measures planned and put into effect.
- Palliative care can help people with advanced disease to have dignity and peace during difficult and final phases of life.
- Freedom from pain can be considered as a human right, yet pain control remains vastly underutilized. The mechanisms for its implementation need to be strengthened.
- Using a broad combination of medical and non-medical methods, pain can be effectively controlled in 90% of cases.
- Patients and their caregivers need training, ongoing support, and supplies for palliative care, including for symptom management at home.

ABOUT THIS CHAPTER

This chapter deals with one of the most important and often neglected components of a comprehensive cervical cancer control programme. It focuses on the importance of having a team of trained, home-based and clinical providers, who can make the end of life of a cancer patient more comfortable and satisfying, and it provides advice on symptom management. The patient's family is considered part of the care team. Most of the issues treated in this chapter are also relevant to patients who need palliative care for other non-curable diseases. Practice Sheets 18–20 provide detailed instructions for management of pain, vaginal symptoms and other common problems encountered in seriously ill patients.



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THE ROLE OF THE HEALTH CARE PROVIDER

The health care provider has an essential role in improving the quality of life of the patient with a life-threatening illness and her family.²⁰ Providers at all levels of the health system need to work as a team, to provide treatment, comfort and care, and to transmit accurate information and skills to the patient, her family and the community. To be able to do this, providers need special focused training in management of both physical and emotional problems, and must have skills in communication and understanding.

STORY



Amelia is a 57-year-old woman from Angola, with 6 children and many grandchildren. She was taken to the nearest district hospital, 95 kilometres away from her home, by her **eldest daughter**, after she developed a vaginal discharge with a very bad odour, which persisted for many months. The doctor who examined her did some tests, and explained that she had advanced cervical cancer which had spread from her cervix to her



vagina and bladder and the walls of her pelvis. The bad odour was caused by urine leaking from her bladder into her vagina and mixing with discharge from the tumour.

The doctor said that unfortunately, at this stage, there was no treatment or cure for her cancer, but that she could be cared for and made comfortable at home. She added that she worked with community health workers near Amelia's village, who provided home-based care for people who were very sick with AIDS, cancer, or other illnesses. Then she wrote a referral note to the woman in charge of the home-based care organization, explaining Amelia's condition and asking her to visit her at home. The doctor said she would work from a distance with the health worker, to make sure that Amelia would have the medicines she needed, including medicine for pain, which might get worse as the cancer progressed. (continued next page)

²⁰ In this context, "family" includes anyone that the patient considers to be significant to her.

Although Amelia and her daughter were shocked and saddened by the news, the doctor's kindness and concern reassured them. Her promise to watch over her care with the local health worker made them both feel more confident and hopeful about the future.



The health worker came as promised; she showed Amelia and her daughter how to deal with some of the problems; how to prepare pads from old, clean cloths to absorb the vaginal discharge, how often to change them and how to wash them, to apply petroleum jelly to the vaginal area as the skin was beginning to get irritated from the constant moisture, to gently wash the area daily with soap and water, and to have sitting baths. With Amelia's permission, she spoke to the family about supporting Amelia and each

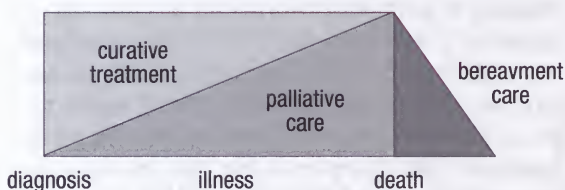
other during her illness, and emphasized the importance of sharing the work as Amelia's condition got worse. There would be more laundry, as bedding and underwear would need to be washed often; the bed should be protected from discharge and urine with a plastic sheet; medicines for pain could be bought at low cost from the local mission hospital, and someone would need to fetch them regularly; other help at home was available through Amelia's church. Amelia's family was poor, but the health worker helped to organize support from the community, the church and the local mission so that the needed supplies were usually there.

She helped the family to understand the importance of keeping Amelia involved in their daily lives, and the life of the community. The family arranged for friends to visit when Amelia felt well enough; they took turns preparing food and, when she became too weak to leave her bed, they made sure that someone was always there for her. Amelia felt that she was not cast aside because of her illness. Even as she approached death, conversation and good spirit kept the house full of life and Amelia felt loved and needed until the end of her life.

A COMPREHENSIVE APPROACH TO PALLIATIVE CARE

Palliative care aims to improve the quality of life of patients and their families facing problems associated with life-threatening illness. Palliative care is not only end-of-life care, but also includes management of all distressing symptoms, including pain. The patient's future needs should be considered at the time she is diagnosed with advanced cancer, so that problems can be anticipated, and prevented or managed (Figure 7.1). Palliative care can be provided by people in the family, community, health centres and hospitals.

Figure 7.1 Continuum of care



Why is palliative care necessary?

Even with the best prevention and screening programmes, some women are diagnosed with advanced disease or will develop such disease, and will need clinical and emotional support and pain control. In many low-resource countries, women are not reached by organized screening programmes and many are diagnosed as having cervical cancer only when they develop symptoms, usually in late stages of disease (see Chapter 6). In addition, facilities for the treatment of cervical cancer may not exist or may not be accessible to many women; as a result, some women with relatively early cancers will not receive the most effective treatment. In these settings, palliative care is particularly important, as many of these women will need relief from pain and other distressing symptoms. Adequate resources have to be made available to care for those who cannot be cured, particularly in rural areas with few health services, where many women will die at home in difficult conditions.

Patients with other chronic severe diseases, such as AIDS, also need special care, and efforts should be made to create a team of health providers at all levels of the health care system with knowledge and skills in palliative care. If appropriate, patients' families should be enrolled into palliative care teams.

RECOMMENDATION

The needs of women with incurable disease should be addressed by using existing palliative care services or establishing new ones. Providers at all levels need to be trained and to have the resources necessary to manage the most common physical and psychosocial problems, with special attention to pain control.

Principles of palliative care

Palliative care:

- provides relief from pain and other distressing symptoms;
- affirms life and regards dying as a normal process;
- is intended neither to hasten nor to postpone death;
- integrates the clinical, psychological and spiritual aspects of care;
- gives the patient and her family as much control and decision-making power as they desire and are able to accept;
- offers a support system to help patients live as actively as possible until death;
- offers a support system to help the family cope during the patient's illness and in their own bereavement;
- uses a team approach;
- will enhance quality of life, and may also positively influence the course of illness;
- is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as surgery and radiotherapy.

Essential components of palliative care

- *Prevention and management of symptoms:* this may include palliative radiation to reduce the size of the tumour, as well as treatment for vaginal discharge, fistulae, vaginal bleeding, nutritional problems, bedsores, fever, and contractures. Families should be taught how to prevent problems, where possible, as well as how to support the patient in her daily activities, such as bathing, going to the toilet, and moving around.
- *Pain relief:* effective pain control can be achieved in 90% of cases, using the medical management described in this chapter, together with ancillary non-medical methods.

- *Psychosocial and spiritual support*: this is an important component of palliative care and requires trained providers with good communication skills.
- *Involving the family*: the health worker can ensure that the patient and her family understand the nature and prognosis of the disease and recommended treatment. The palliative care worker must also be able to help the patient make decisions about her care. The patient and her family should have sense of being in control, with full support from the health care team, whose task is to provide appropriate information and advice and support informed decisions.

Palliative care requires systematic and continuous application of the five steps (five “A”s), described below. Like other aspects of cervical cancer care, this approach requires teamwork and adequate resources.

The five As of palliative care: Assess, Advise, Agree, Assist and Arrange.

Assess:	Assess the patient's status and identify the treatments needed; assess the patient's and carers' knowledge, concerns and skills related to the illness and the treatment.
Advise:	Explain how to prevent and manage symptoms, and teach needed skills, a few at the time, by demonstration and observed practice.
Agree:	After giving information and teaching skills, make sure that the patient knows what to do and that she wants to do it. Empower her to stay in charge. Support patient self-management and family care.
Assist:	Make sure the patient and her family have enough supplies to cope with difficult situations and give required care. Give written instructions as a reminder of what has to be done, with pictures if needed for those who cannot read.
Arrange:	Schedule a time for the next visit. Make sure the patient, her family and other carers know where to go if they have questions or concerns.

Make sure the family knows when and who to call for help.

The role of the family in palliative care

Palliative care should be available wherever patients are – at home, in hospitals, in hospices, etc. In developing countries, most patients die at home, and the family plays an important role in palliative care. If the patient agrees, and if appropriate, the patient's family should be involved and empowered in joint decision-making, should be constantly kept informed of medical decisions, including changes in carers and treatment, and should be trained in best practices of palliative care. The patient's family and other carers can be taught to give home-based care. Clinical care should be provided by health workers trained to use recommended medicines within the national legal framework. Providers of palliative or home-based care should have continual back-up from first-level health workers (physician, clinical officer, or nurse) who should be available for consultation or referral when needed.

Accessing local resources for care at home

When a woman is no longer able to work or care for her family, meagre resources may become further stretched. Money for food, supplies and medicines for her care or the supplies themselves are sometimes available through local, regional or national nongovernmental organizations, faith-based organizations, women's groups and community-based organizations. A palliative care or home-based care (HBC) programme should have links with these organizations where possible, and provide referrals for women and their families.

MANAGING COMMON SYMPTOMS OF EXTENSIVE CANCER

Women with advanced cancer can suffer a constellation of physical, psychological and emotional problems. Pain is almost always part of the constellation, and its relief should always be part of palliative care.

Pain management

Pain relief for cancer patients:

- is vastly underutilized and, as a result, many patients suffer needlessly;
- is achievable and inexpensive;
- needs cooperation and two-way communication between home-carers and clinical providers at all levels of the health care system.

Home-carers are most in touch with the patient's needs, while clinical providers can offer support and medications.



Pain management

The following are the major barriers to effective pain relief:

- lack of awareness, on the part of health care providers and the general public, that pain relief is achievable and inexpensive.
- lack of availability of pain medications as a result of restrictive regulatory policies. Even when controlled pain medications (opiates and oral morphine) are available in principle, providers – including physicians – may be restricted by national drug control policies from prescribing or dispensing them.
- providers' unrealistic fears of promoting drug dependence in patients, and of contravening drug enforcement laws.

National rules and regulations must be followed. They should be carefully checked to see whether they allow pain relief to be administered by non-medical people under the supervision of doctors or nurses. If not, medical and non-medical people need to join forces to advocate for patients' right to freedom from pain.

In the context of palliative care in national cancer control programmes, restrictive drug regulations need to be modified to allow access to pain control. Although changing policy and law is not the role of the care team, providers should advocate for, and demand, policy change, to remove barriers to access to pain relief, including opioids.

RECOMMENDATION

A comprehensive cervical cancer control programme should ensure that opioid, non-opioid and adjuvant analgesics, particularly morphine for oral administration, are available.

WHO's analgesic ladder

WHO has developed an effective and relatively inexpensive method for relieving cancer pain in about 90% of patients. This method is called the WHO ladder for cancer pain relief and is described in Practice Sheet 18. It can be summarized as follows:

- by mouth: whenever possible, analgesics should be given orally in order to permit wide applicability of this method;
- by the clock: analgesics should be given at fixed time-intervals. The next dose should be given before the effect of the previous one has fully worn off, to ensure continuous pain relief;
- by the ladder: the first step is to give a non-opioid, typically paracetamol. If this does not relieve the pain, opioids for mild to moderate pain, such as codeine, should be



Pain management

given. The third step is to give opioids for severe pain, such as morphine. Additional drugs, called adjuvants, can be used in certain circumstances; for example, psychotropic drugs may be given to calm fear and anxiety;

- for the individual: there is no standard dose for opioid drugs. The right dose is the dose that relieves the patient's pain.

Two rules for opiate dosage:

There is no standard dose for opioid drugs: the right dose is the dose that relieves pain. There is no ceiling dose for opioid drugs: the dose will gradually need to be increased as patients become tolerant to the pain-relieving effects.

In cervical cancer patients, pain management will depend on the body part involved. Table 7.1 outlines management of some commonly encountered pain syndromes.

Table 7.1 Pain syndromes in cervical cancer and their management

Syndrome, clinical features	Pain probably caused by:	Treatment
Tenderness over a bone, may be worse on movement (severe pain or tenderness in weight-bearing bones needs urgent attention to prevent fractures)	Metastases in bone	• Radiotherapy • Bisphosphonates • Surgery (e.g. pins) for weight-bearing bones • NSAIDs* ± paracetamol (if no contraindications) always needed • Corticosteroids, if NSAIDs are contraindicated • Opioids if pain still present
Leg calf and foot pain, possible loss of strength	Involvement of lumbosacral nerve plexus	• NSAIDs ± paracetamol • Steroids: dexamethasone 4 mg for 1 or 2 days, then 2 mg a day • Opioids • ± Tricyclic antidepressants or an anticonvulsant
Pain when leg flexed at hip (Psoas sign) Leg pain	Infiltration of psoas muscle	• Same as above but diazepam or other antispasmodic essential

*Nonsteroidal anti-inflammatory drugs.

Non-medical methods to assist in pain control

Many non-medical methods, appropriate to local customs and culture, can help control pain. These methods can be used together with pain medications but should never take the place of effective pain-relieving medicines. Non-medical pain management may include: emotional support, physical methods (touching and massage), distraction, prayer, meditation and other non-harmful local traditional methods. They should be provided only with the explicit understanding and approval of the patient and her family.

Prevention and management of other problems of advanced disease

Problems to be managed at home may include:

- vaginal discharge,
- fistulae,
- vaginal bleeding,
- nausea and vomiting,
- diarrhoea or constipation,
- fever,
- loss of appetite, wasting, weakness and fatigue,
- leg swelling,
- bedsores,
- shortness of breath,
- depression.



PS 19 Home-based care
PS 20 Managing vaginal discharge

DEATH AND DYING**Anticipating practical issues**

To help the patient and her family bear the burden of imminent death and bereavement, home-care providers can encourage discussion of important issues, such as writing a will, financial support of the family, changing roles within the family and reconciliation of old quarrels.

Preparing for death

Encouraging communication within the family can make a death less stressful and ease bereavement (see Chapter 6 for additional advice on how to talk with the incurable patient and her family). At times, the patient may express anger or other strong emotions towards her closest family members and the health care provider; such outbursts need to be accepted and not taken personally.

The trained provider can help the dying woman by doing the following:

- helping her deal with guilt or regret;
- talking about her impending death;
- providing comfort and care;
- responding to grief reactions, such as denial, sadness, bargaining, yearning, anger, humiliation, despair, guilt and acceptance;
- keeping communications open, and giving her the chance to talk about her feelings, without pressuring her if she is not ready to talk;
- offering practical support, such as helping to make a will;
- asking her how she wishes to die (where, and with only family present or with pastoral care);
- making sure that her wishes are respected.

When considering the possibility of transferring the patient to the hospital, carers should take into account her wishes and those of her family. It is probably not appropriate to transfer a dying patient, unless she requests it.

Death

At the time of death, it is essential to respect local rites and rituals, as well as the previously expressed personal wishes of the patient concerning care of the body, funeral, and other issues.

Bereavement

Bereavement care is support given to the family after a patient's death, to help them accept the loss of their loved one. Home-care workers and clinic providers involved in the woman's terminal care can share the family's sorrow, by encouraging them to talk and express their memories. Workers should not offer false comfort but should be supportive, take time to listen, and try to arrange practical support with neighbours and friends.

ORGANIZATION OF PALLIATIVE CARE SERVICES

In resource-poor settings, palliative care is most often provided by untrained community health workers.

To be effective, these workers require:

- training in clinical and psychological palliative care, which can be given in 1–3 weeks for those with basic medical skills;
- supportive supervision from hospice nurses or others trained in the management of psychosocial and medical problems in severely ill patients;
- essential medicines and other supplies needed for effective palliative care, provided according to a national essential drug list. The primary health care facility can arrange for regular supplies for home-based care providers and their patients;
- a secure place to store medicines, and a separate tracking system for pain medications, if this is required by the drug regulatory authority;
- open communication with the formal health system, and access to more skilled providers for consultation and referral of patients when needed.



Home-based care

A team approach to palliative care

Providers at all levels of care, from specialists to home-care providers, should work together to ensure the best quality of life and outcome for the patient with advanced cervical cancer. In tertiary care settings, the team might include a gynaecologist, a radiotherapist, a radiotherapy technician, a psychologist or counsellor, a nutritionist, a physiotherapist, an oncology nurse, a pharmacist, a social worker and a palliative care nurse. In resource-poor settings it is unlikely that such a highly specialized team can function down to the level of the community where the woman lives. Strategies need to be devised for individual community providers responsible for the patient's continuing care, to allow them to link the patient and her family with staff at the health centre and district and central hospitals.

PALLIATIVE CARE AT DIFFERENT LEVELS OF THE HEALTH SYSTEM

In the community



- Visit the patient's home on a regular, scheduled basis, in order to anticipate and follow up problems.
- Facilitate access to supplies and medicines.
- Teach care and comfort-giving procedures to the patient and her family and check that they are being done.
- Answer questions, provide information and keep records.
- Encourage the family to keep the patient involved in their daily life as much as possible.

At the health centre



- Supervise, support and maintain supplies for the CHWs who do home visits for women with cervical cancer.
- Provide emergency or routine follow-up care for problems after diagnosis or treatment for invasive cancer.
- Manage referrals to other facilities for palliative care.

At the district hospital



- Maintain contact with health centre and palliative care providers, and follow up women referred from this level.
- Support and supervise the team at lower levels.
- Provide treatment and care.
- Refer patients to central level for acute problems that are best managed there, such as uncontrolled vaginal bleeding and intractable pain.

At the central hospital



- Be involved in palliative care services organized at district and primary facility levels. Assist, train and supervise lower-level providers and CHWs.
- Provide certain palliative procedures, e.g. radiotherapy.
- Counsel and educate the family and patient in how to prevent common problems, such as contractures and bedsore.
- Participate in the development of an individualized home-based care plan for each patient. Refer patients back to facilities closer to their home, instructing the facilities and providing distance supervision. Be available for consultations by telephone or mail.
- Write prescriptions for medications such as analgesics, including oral morphine, and give them to the patient or her carers for immediate or future use.
- Visit the community from time to time to conduct training sessions for HBC workers or CHWs, and to learn from them about the conditions in which they work, and in which their patients live.

ADDITIONAL RESOURCES

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PRACTICE SHEET 18: PAIN MANAGEMENT

PS 18

Practice Sheet 18: Pain Management

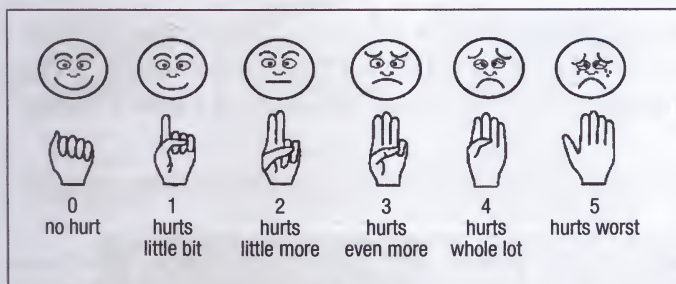
This Practice Sheet details clinical actions to relieve pain. See also Table 7.1 for additional suggestions on pain management.

Freedom from pain can be considered a human rights issue

MANAGING PAIN²¹

1. Assess the patient's pain. If possible, determine the cause, identify any new pain and any change in pre-existing pain. Ask the patient questions to determine the following:
 - Where is the pain? What makes it better or worse? What type of pain is it?
 - What is the patient taking for the pain?
 - Is there a psychological or spiritual problem in addition to a physical, cancer-related reason for the pain? Is the patient worried, fearful, depressed or grieving?
 - How bad is the pain? Fingers or faces can be used to grade the pain (Figure PS18.1).

Figure PS18.1 Assessing pain by using fingers or faces



2. Record your findings on the patient's chart and your own record.
3. If you find the cause of the pain, treat the cause if possible (bone pain, muscle spasm, gastrointestinal pain from constipation, swelling around tumour).

²¹ Adapted from: *Palliative care: symptom management and end-of-life care. Interim guidelines for first-level facility health workers*. Geneva, WHO, 2004 (WHO/CDS/IMAI/2004.4 Rev.1).

PS18

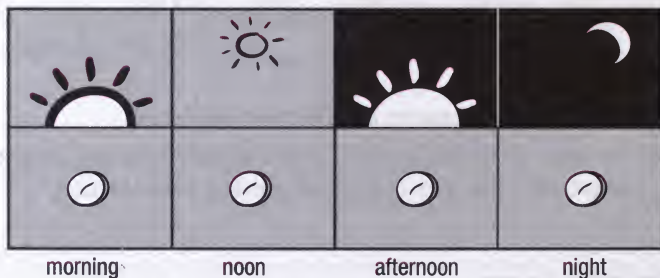
4. Use analgesics according to the recommendations below.
5. In addition, you may use appropriate, non-medical treatment, as long as it is not harmful. Non-medical treatment should not replace medical management.
6. Check frequently the patient's need for pain-relieving medication, especially if the pain becomes more severe.

Teach the woman and her carers how to use pain-relieving medications. Check often to make sure that she is receiving the right doses of the right medicines at the scheduled times.

Pain should be treated using the WHO ladder for cancer pain relief (see Figure PS 18.3), and the following principles:

1. Treatment should be provided by mouth or rectally. Injections should be avoided whenever possible.
2. Medicines should be given at fixed time intervals (calculated by the clock, the radio or the sun). Each dose of medicine should be given before the previous dose wears off. Give the first dose when the patient wakes up, and the last dose just before she goes to sleep; do not wake a person who is sleeping comfortably to give medications. The bedtime dose can be doubled if needed.
3. If pain returns before the next dose is due, immediately give a "rescue" dose (the same dosage as the regular dose). This is in addition to the next scheduled dose, not in place of it.
4. The dose of pain medication should be calculated and adapted where necessary in order to control the pain while keeping the patient as alert as possible.
5. Write out a detailed schedule for each drug, with words or in a drawing (Figure PS18.2).

Figure PS18.2 Example of a drawing that can be used to show the schedule of drug intake



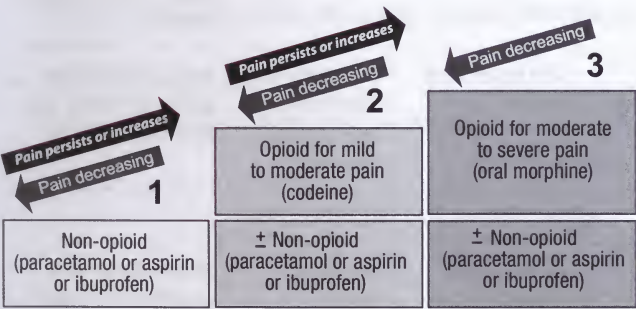
Keep in mind: There is no such thing as an established dose for all patients. Medical personnel and home-carers need to establish, with the patient, her need for medication, based on the amount of pain she has. The right dose is the dose that relieves pain; it will gradually need to be increased because patients become tolerant to the medicine's effects.

How to give medicines for pain

- 1. Start with a non-opioid, such as paracetamol, aspirin or ibuprofen.
- 2. If the pain persists or increases, give an opioid for mild to moderate pain, e.g. codeine, with or without a non-opioid (paracetamol, aspirin or ibuprofen). When opioids are prescribed, you should systematically give a laxative to prevent constipation. Add an anti-emetic if necessary.
- 3. If pain persists or increases, give morphine, with or without an additional non-opioid.

Note: in most countries, opioids require medical prescription and supervision.

Figure PS 18.3 WHO's pain relief ladder



Source: Palliative care: symptom management and end-of -life care. Interim guidelines for first-level facility health workers. Geneva, WHO, 2004 (WHO/CDS/IMAI/2004.4 Rev.1).

In what dose and how often should medications for pain be given?

PS18

Medication	Starting dose	Dose range	Side-effects/ precautions
NON-OPIOID FOR MILD PAIN			
Paracetamol	2 tablets of 500 mg, every 4–6 hours	1 tablet may suffice in very ill patients, or in combination with opioid. Maximum dose 4000 mg daily	Can cause liver toxicity
Aspirin	600 mg (2 tablets of 300 mg) every 4 hours		Avoid if patient has gastric problems or vaginal bleeding; stop if patient has stomach pain, indigestion, black stools, small bruises, bleeding
Ibuprofen	400 mg every 6 hours	Maximum dose 3000 mg (7.5 tablets of 400 mg) daily	Avoid if patient has gastric problems; give with food if possible
OPIOID FOR MILD TO MODERATE PAIN			
Codeine (if not available, alternate aspirin and paracetamol)	30 mg, every 4 hours	30–60 mg every 4–8 hours	Give laxatives from the beginning to avoid constipation Can be costly
OPIOID FOR MODERATE TO SEVERE PAIN			
Morphine liquid, 5 mg/ml or 50 mg/5 ml Drop into mouth from syringe; can be given rectally using syringe (no needle)	2.5–5 mg every 4 hours (if pain persists increase dose by 1.5 or 2 times after 24 hours)	According to patient need, and breathing There is no ceiling dose	Give laxatives to avoid constipation Reduce dose if breathing problems occur

NON-MEDICAL METHODS TO ASSIST IN PAIN CONTROL

A number of methods, appropriate to local customs and culture, can be very important in helping the patient cope with pain. These methods may be used in addition to effective modern medicines, and should never take their place.

Non-medical methods may include:

- emotional support: the care and support of family and friends are most important in relieving discomfort during severe illness;
- touch, such as stroking, massage, rocking and vibration;
- distractions, such as radio, music and helping the patient to imagine a calm scene or a happy event in her life;
- prayer and meditation, according to the patient's practice.

Traditional practices, if not harmful, can be very beneficial.

The attitude of the health care provider is also important:

- Listen with empathy.
- Try to understand her reactions to her illness (the different stages of grief).
- Refer to a spiritual counsellor or pastoral caregiver, according to her religion and wishes.
- Avoid imposing your own views.
- Empower the family to continue to provide care.

PS18

Practice Sheet 18: Pain Management

PRACTICE SHEET 19: HOME-BASED PALLIATIVE CARE²²

This Practice Sheet summarizes recommendations for supportive home-care for severely ill cervical cancer patients.

- You can adapt it to the role you play in palliative care for a patient.
- Your objective is not to cure the patient, but rather to make her life more comfortable by reducing the severity of symptoms and side-effects of the illness and the treatment.
- You can use these recommendations with people with any advanced or terminal illness.
- You need to be conscious of the important contribution to patient comfort provided by physical, emotional, spiritual and alternative measures, e.g. massage, stroking, distractions, such as music, prayer and meditation, and local traditional practices.
- The patient herself must decide if she or someone else will use the available alternatives to treat her problems.

Particularly when medications are needed, the support of nurses and doctors is essential.

Management of common symptoms of advanced disease

Problem/ Symptoms	Cause	Prevention	Clinical management	Home-care
Vaginal discharge, which may be foul-smelling (see also Practice Sheet 20)	Tumour necrosis Fistula Bacterial overgrowth	Difficult to prevent Palliative radiation or surgery of tumour	Pack vagina twice a day with cloths soaked in vinegar, sodium bicarbonate (baking soda) or metronidazole. Give antibiotics and/or antifungals, if necessary	Frequent sitting baths Clean, absorbent pads changed often Douching

²² Adapted from: *Palliative care for women with cervical cancer: a field manual*. PATH, EngenderHealth, 2003; and *Palliative care: symptom management and end-of-life care. Interim guidelines for first-level facility health workers*. Geneva, WHO, 2004.

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Problem/ Symptoms	Cause	Prevention	Clinical management	Home-care
Vesicovaginal or rectovaginal fistula (symptoms: leaking urine or faeces from the vagina; vulvar irritation) (see also Practice Sheet 20)	Tumour creates passage between bladder or rectum and vagina	Difficult; a common problem of late invasive cancer	None	As above Keep patient clean and comfortable Zinc ointment or petroleum jelly to protect anus and vagina Plastic or newspaper under bedding for protection
Vaginal bleeding (see also Practice Sheet 20)	Bleeding tumour	Palliative radiotherapy	Pack vagina if needed	Rest; avoid strenuous activity and sexual intercourse
Nausea or vomiting	Opioids Gastrointestinal infection Severe pain Fever Radiation Chemotherapy Renal failure	Give anti-emetics when starting opioids and as needed, to prevent nausea	Metoclopramide or promethazine orally or rectally (by injection only if absolutely necessary)	Small, regular sips of rehydration drinks, ginger tea, ginger ale or cola drinks, as tolerated

Problem/ Symptoms	Cause	Prevention	Clinical management	Home-care
Diarrhoea	Gastrointestinal infection, parasites, radiotherapy	Good food hygiene, handwashing; use clean or boiled drinking-water	Treat cause if known Loperamide	Fluids, oral rehydration salts solution, food as desired; keep clean; prevent skin problems
Fever: body temperature $>37^{\circ}\text{C}$	Bacterial infection (lymphangitis, kidney, lung, etc.)	Prevent infections where possible	Treat cause, using most appropriate antibiotics Paracetamol	Remove blankets; ventilate room; sponge baths; paracetamol
Constipation	Opioids, poor intake of fluids and solids, immobility	Encourage fluids, high-fibre diet, mobility, regular use of stool softeners and laxatives	Modify diet; give laxatives with opioids	Modify diet; give laxatives with opioids
Loss of appetite, wasting	Illness, medications	Small frequent meals, desired food only, fresh foods	Can use corticosteroids	Can use corticosteroids
Weakness, fatigue	Illness, normal postoperative recovery, anaemia, wasting	Good general care	Treat cause if possible	Good general care

PS19

Practice Sheet 19: Home-based Palliative Care

Problem/ Symptoms	Cause	Prevention	Clinical management	Home-care
Leg swelling	Lymph blockage from tumour, lymphangitis, kidney failure		Antibiotics, if infection is suspected	Wrap leg and elevate, massage
Bedsore	Constant pressure breaks down skin	Daily bathing, turn patient every 2 hours, soft padding underneath, cushions, massage	Wash sores with antiseptic twice a day, remove dead tissue, cover with clean bandage; if infected give oral antibiotics	Daily bathing, frequent turning. Clean sores gently every day with diluted saltwater. Fill the bedsore area with pure honey and cover with a clean light dressing to encourage healing
Cough, breathing problems	Pneumonia, bronchitis, viral upper respiratory tract infection, tuberculosis, heart failure	If family member is sick, ensure good ventilation in home	Treat cause if known	Increase fluids, home cough remedies, sit patient upright, codeine
Depression, anxiety	Illness, grief reaction	Family and spiritual support, pain control	Counselling or support around cause, if any; amitriptyline for depression; diazepam for anxiety	Continued support, time spent with her doing things she likes, prayer

When to transfer a patient for care and emergency treatment of acute symptoms

If the patient has any of the following, consider transferring her to hospital for emergency care:

- severe vaginal bleeding;
- signs of severe dehydration:
 - pulse > 100/minute,
 - fast breathing,
 - no urine for over 24 hours;
- severe diarrhoea for more than 48 hours;
- blood in stool;
- fever over 39 °C for over 48 hours;
- convulsions;
- confusion;
- severe abdominal pain, gastrointestinal obstruction (swollen, very painful abdomen, no defecation for over 48 hours);
- severe pain, not controlled with opioids;
- multiple infected bedsores;
- acute respiratory distress;
- attempted suicide.

The patient (if conscious) and her immediate family need to be involved in the decision to transfer her. ***If the woman is dying, she should not be transferred at the last minute.***

PS19

PRACTICE SHEET 20: MANAGING VAGINAL DISCHARGE AND FISTULAE AT HOME

PS 20

This Practice Sheet explains how to provide care and comfort for women with vaginal problems, resulting from advanced invasive cervical cancer and complications of treatments. It includes management of vaginal discharge, fistulae and bleeding.

In addition to the specific advice in this sheet, supportive, emotional and other non-medical measures can be very effective.

Managing vaginal discharge

Women with cervical cancer may have watery, bloody, foul-smelling vaginal discharge. This symptom is a result of bacterial growth in the unhealthy tissues of the lower genital tract. The bacteria produce gas.

The bacteria cannot be permanently eliminated, but symptoms can be temporarily alleviated by doing one or more of the following.

- Absorb the discharge with clean cloths, cotton or menstrual pads, placed in the panties.
- Carry out periodic, *careful* vaginal douching (rinsing the vagina using a tube attached to a clean plastic bottle or syringe), using one of the following solutions:
 - one tablespoon of sodium bicarbonate (baking soda) in two cups of boiled warm water; or
 - one part vinegar in 4 parts water; or
 - 5–10 crushed tablets of metronidazole dissolved in 2 cups of boiled warm water.
- *Gently* pack the vagina twice a day with clean cloths soaked in one of the above solutions. Packs should not be left in place for more than a few hours.²³
- Broad-spectrum antibiotics may be prescribed by a physician, but they should be used with caution because they are, at best, only temporarily effective. In addition, they can cause a yeast infection in the vagina, which can make symptoms worse. The patient and family must be made aware of the importance of completing any prescribed antibiotic regimen; not completing it may worsen the problem. The following antibiotics can be given during a minimum of 5 days: doxycycline, 100 mg by mouth, twice a day; or amoxicillin, 250 mg by mouth, 3 times a day; or metronidazole, 400 mg by mouth, twice a day.

²³ To avoid making the problem worse, whenever something is inserted into the vagina (douche tube, packing), the utmost gentleness must be used.

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Managing fistulae

A fistula is an abnormal passage between the vagina and urinary bladder or rectum, caused either by extension of the cancer into these organs or as a complication of radiotherapy. It is a psychologically and physically debilitating condition, because urine or faeces may pass directly to the vagina, causing a foul-smelling and irritating discharge.

The fistula itself cannot be repaired, but the patient can be made more comfortable and clear:

- She can sit in warm water to gently clean herself.
- Soft clean cloths can be placed in her panties to absorb the discharge.
- Cover the bed with a plastic sheet or newspapers, which can be changed and cleaned frequently.
- Protect the skin around the vagina and anus by drying the areas after bathing and covering them with zinc oxide cream or petroleum jelly. These measures can be used in a preventive way, without waiting for irritation to occur.
- Ventilate the room or burn incense or herbs, if this is acceptable.

Managing vaginal bleeding

Vaginal bleeding can be alarming and is not uncommon in women with advanced cervical cancer. It can be triggered by sexual intercourse or strenuous activity, or it may occur spontaneously for no obvious reason.

- If bleeding is slight, recommend bed rest and cleanliness until it stops.
- If bleeding is moderate, it often subsides with simple bed rest. If needed, the vagina can be packed with a clean moistened cloth for a few hours.
- If bleeding is severe, transfer the patient to a hospital or health centre for a possible blood transfusion.

Supplies for home-based management of vaginal problems

The following supplies are needed:

- a constant supply of clean, boiled water;
- soap for washing hands and clothes;
- clean towels;
- latex gloves, if possible (need not be sterile);
- plastic sheeting or newspapers;

- bags for disposal of contaminated materials;
- chlorinated water (one cup of bleach to 6 cups of water) for soaking gloves, wiping down furniture and plastic sheeting, etc.;
- a basin for sitting baths;
- a plastic bottle and tube for douching;
- plenty of clean cloths, or cotton or menstrual pads (if possible). These should be boiled if they are going to be used to pack the vagina;
- sodium bicarbonate (baking soda);
- vinegar;
- zinc oxide cream or petroleum jelly;
- antibiotics and other medicines prescribed by the physician (metronidazole, doxycycline, amoxicillin).

COUNSELLING TIPS

- Visit the patient as often as possible.
- Always listen to the patient's and the family's complaints, and try to relieve symptoms.
- Maintain communication with providers in the health centre or hospital and seek their advice for specific problems.
- Provide comfort and security by explaining the reasons for the symptoms and reassuring the family that you will do all you can to keep the patient comfortable.
- Instruct the patient and family in symptom management.
- Assist them in obtaining needed supplies.
- Most importantly, try to avoid burn-out for yourself by avoiding overwork, maintaining close relationships, and seeking the support of those close to you (without breaching patient confidentiality).

PS20

Practice Sheet 20: Managing Vaginal Discharge and Fistulae at Home

ANNEX 1: UNIVERSAL PRECAUTIONS FOR INFECTION PREVENTION²⁴

A1

Annex 1: Universal precautions for infection prevention

Universal precautions are simple measures that help prevent the spread of infection. All health care providers must use universal precautions to protect patients, themselves and other health care workers from the spread of infectious diseases.

The current epidemic spread of bloodborne viruses, including hepatitis B, C and D, and HIV, underscores the importance of paying scrupulous attention to preventing infection in clinical practice. Many transmissible infections are asymptomatic, and it is not always possible to know who is infected. Therefore, precautions against spreading infection should be used with all patients, whether they appear sick or well, and whether their HIV or other infection status is known or not.

Quality control and supervision are essential to ensure that infections are prevented. A pelvic infection after a clinical procedure is an indicator of poor infection-prevention measures.

Infection prevention: universal precautions

Wear latex gloves whenever:

- you handle items or body surfaces that might be contaminated;
- you perform clinical examinations or procedures (cryotherapy, biopsy, endocervical curettage and LEEP), or give injections;
- you clean the area where the patient has been;
- you handle used instruments.

Remember:

- If gloves get damaged, remove them, wash your hands thoroughly, and then put on new gloves.
- Gloves are not a substitute for handwashing.

Wash your hands with soap and water for at least 30 seconds:

- before and after contact with each client or patient;
- if you touch blood or body fluids;
- immediately after you take off latex gloves.

²⁴ Adapted from: *Universal precautions against infectious diseases*. University of Michigan Health System (www.med.umich.edu/1libr/wha/wha_unipre_crs.htm); and Burns AA et al., *Where women have no doctor*. Berkeley, CA, Hesperian Foundation, 1997.

Handle contaminated disposable items and clinic surfaces as follows:

- Discard disposable items that are soiled with blood or body fluids in a tightly sealed plastic bag.
- Disposable needles need special handling; use your health facility's protocols.
- Wash linen and reusable cloth items. Use detergent, dry them in the sun, and iron them if possible.
- Clean and disinfect surfaces such as examination tables and floors.

Process reusable instruments and gloves after each use, as follows:

- All instruments that have been in contact with the vagina or cervix (e.g. specula, biopsy forceps, gloves, etc.) should be decontaminated, cleaned, and sterilized or high-level disinfected.
- Cryoprobes should be decontaminated, cleaned, and high-level disinfected.
- The examination or procedure table must be decontaminated after each patient. Other instruments (e.g. colposcope, cryogun, torch lights) must be decontaminated at least once a day, and more often if visibly soiled.

Processing instruments²⁵

There are three basic steps for processing instruments used in clinical and surgical procedures, before they can be reused: (1) decontamination, (2) cleaning, and (3) sterilization or high-level disinfection (HLD).

Decontamination

Decontamination is the process by which used instruments and gloves are made safe for handling; this step inactivates hepatitis B and HIV. To decontaminate instruments and gloves immediately after use, immerse them in a large plastic bucket containing 0.5% chlorine solution for 10 minutes (not longer, as the instruments may become corroded); remove and rinse with clean water. The chlorine solution can be prepared by diluting 1 part household bleach in 9 parts clean water. It must be prepared fresh daily and discarded as soon as it appears dirty. For surfaces in the clinic, 60–90% ethanol or isopropanol can be used as an alternative to chlorine solution.

Cleaning

Soon after decontamination, instruments should be cleaned by a person wearing heavy gloves and glasses or goggles. Use a brush to scrub instruments with water and detergent, and rinse thoroughly with boiled water. Special attention must be given to instruments with teeth, joints and screws.

²⁵ Adapted from: Sellors JW, Sankaranarayanan R, *Colposcopy and treatment of cervical intraepithelial neoplasia: a beginners' manual*. Lyon, IARC Press, 2003.

Sterilization

Sterilization destroys all microorganisms and must be used for all instruments that come into contact with sterile parts of the body, e.g. that penetrate the skin or enter the womb.

Sterilization can be achieved by one of the following:

- Expose instruments to superheated steam in an autoclave: 20 minutes for unwrapped instruments and 30 minutes for wrapped instruments. Autoclaving is the preferred method of sterilization.
- Soak instruments in either 2–4% glutaral for 8 to 10 hours, or 8% formaldehyde for 24 hours. Then rinse thoroughly with sterile water.

High-level disinfection

HLD destroys all organisms except bacterial spores, and is used when sterilization equipment is not available or the instrument is too delicate to be sterilized. One of the following processes can be used for HLD:

- Boil instruments for at least 20 minutes in plain tapwater, which is changed at least daily. Make sure that instruments are fully covered by the water, and start timing after the water with the instruments is fully boiling. Do not add anything to the pot once you have started to time.
- Soak instruments in 0.1% chlorine or 2% glutaral solution for 20 minutes, or 6% hydrogen peroxide for 30 minutes. Rinse thoroughly in boiled water, air-dry and store in a sterile cloth. These chemicals may be corrosive and can reduce the useful life of instruments that are repeatedly disinfected with them.

Supplies and equipment

The following supplies and equipment are needed for infection prevention (depending on the processing methods used):

- clean and boiled water;
- detergent;
- household bleach or commercial chlorine powder;
- one or more sterilizing chemicals (2–4% glutaral, 8% formaldehyde);
- one or more HLD chemicals (0.1% chlorine, 2% glutaral, 6% hydrogen peroxide);
- 60–90% ethanol or isopropanol;
- sterile cloths;
- plastic bucket;

(continued next page)

- scrubbing brush;
- large jars for storage of solutions;
- heavy gloves for cleaning;
- sterile or high-level disinfected gloves and long-handled forceps for handling processed instruments;
- autoclave or vessels for boiling and soaking instruments;
- closet with tight closure to prevent entrance of dust, for storage of processed instruments and supplies.

A1

ANNEX 2: THE 2001 BETHESDA SYSTEM²⁶

SPECIMEN ADEQUACY

- Satisfactory for evaluation (note presence or absence of endocervical transformation zone component).
- Unsatisfactory for evaluation (specify reason).
- Specimen rejected/not processed (specify reason).
- Specimen processed and examined, but unsatisfactory for evaluation of epithelial abnormality because of....(specify reason).

GENERAL CATEGORIZATION (OPTIONAL)

- Negative for intraepithelial lesion or malignancy.
- Epithelial cell abnormality.
- Other.

INTERPRETATION AND RESULT

Negative for intraepithelial lesion or malignancy

Organisms:

- *Trichomonas vaginalis*;
- fungal organisms morphologically consistent with *Candida* species;
- shift in flora suggestive of bacterial vaginosis;
- bacteria morphologically consistent with *Actinomyces* species;
- cellular changes consistent with herpes simplex virus.

Other non-neoplastic findings (optional to report, list not comprehensive):

- reactive cellular changes associated with inflammation (includes typical repair);
- radiation;
- intrauterine contraceptive device;
- glandular cells status post-hysterectomy;
- atrophy.

²⁶ This categorization can be used for reporting results of Pap smears.

Epithelial cell abnormalities

Squamous cells

- Atypical squamous cell (ASC):
 - of undetermined significance (ASC-US);
 - cannot exclude high-grade lesion (ASC-H).
- Low-grade squamous intraepithelial lesion (LSIL).
- High-grade squamous intraepithelial lesion (HSIL).
- Squamous cell carcinoma.

Glandular cells

- Atypical glandular cells (AGC) (specify endocervical, endometrial, or not specified).
- Atypical glandular cells, favour neoplastic (specify endocervical or not specified).
- Endocervical adenocarcinoma in situ (AIS).
- Adenocarcinoma.

Other (list not comprehensive)

- Endometrial cells in women 40 years of age or over.

ANNEX 3: HOW IS A TEST'S PERFORMANCE MEASURED?

A test's performance is measured in terms of its reliability and accuracy in predicting disease. The ability to predict disease depends on two key characteristics: sensitivity²⁷ and specificity.

- *Reliability* is the degree to which repeated measurements yield the same result, and can be reproduced in other settings.
- *Sensitivity* refers to the ability of the test to correctly identify individuals with the condition, in this case precancer or cancer. The higher the sensitivity, the fewer women with precancer or cancer will be wrongly identified as normal (false negative).
- *Specificity* refers to the ability of the test to correctly identify individuals without precancer or cancer. The higher the specificity, the fewer women with a normal cervix will be wrongly identified as having precancer or cancer (false positive).

An ideal screening test would have both high sensitivity and high specificity. Such a test does not currently exist for cervical precancer and cancer. The danger of low sensitivity is that some women with disease will be missed; the danger of low specificity is that some women without disease may be unnecessarily referred for further diagnosis or treatment.

Women might also want to know the likelihood of really having the disease when they have a positive screening test. This is the *positive predictive value* (PPV) of the test. The *negative predictive value* (NPV) is the chance of not having the disease when the test is negative. Unlike sensitivity and specificity, which are in general intrinsic features of the test, the PPV and NPV depend on the prevalence of disease in the population.

Calculation of specificity, sensitivity, PPV and NPV

Result of screening test	True disease state ²⁸		
	Positive	Negative	
Positive	a	b	a+b
Negative	c	d	c+d
	a+c	b+d	a+b+c+d

Sensitivity = $a/a+c$; specificity = $d/b+d$; PPV = $a/a+b$; NPV = $d/c+d$.

²⁷ In this guide, the reported sensitivity and specificity of screening tests for cervical precancer and cancer are calculated using a histological result of CIN2 or higher as the threshold (see Chapter 2).
²⁸ The "gold standard" for true disease state in the diagnosis of cervical precancer is the histological result of the biopsy.

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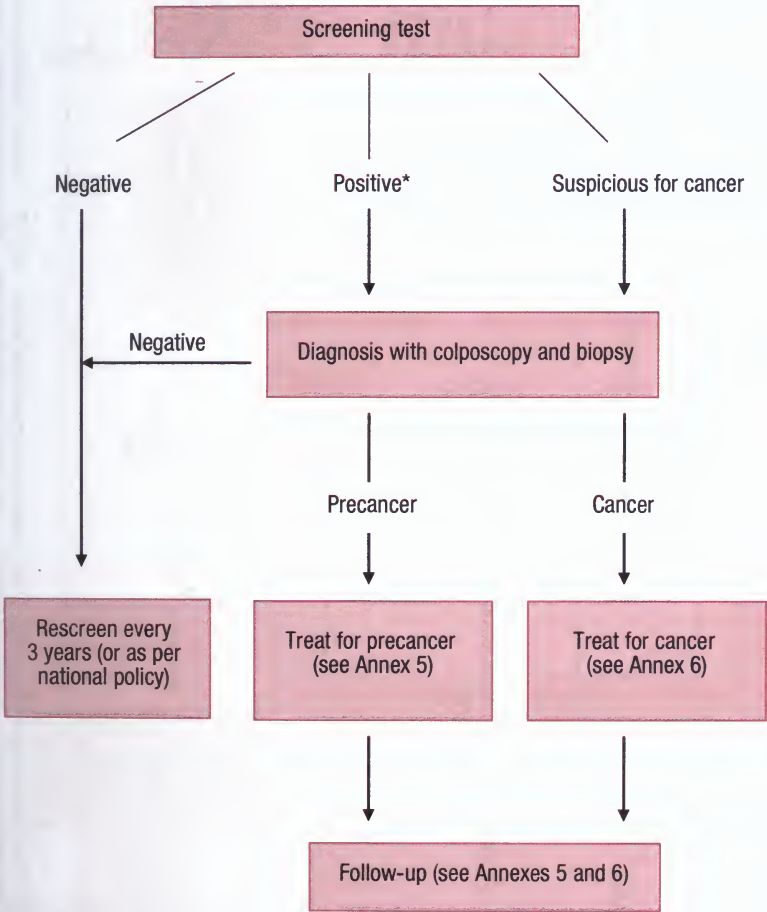
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ANNEX 4: FLOWCHARTS FOR FOLLOW-UP AND MANAGEMENT OF PATIENTS ACCORDING TO SCREEN RESULTS

4a. STANDARD APPROACH

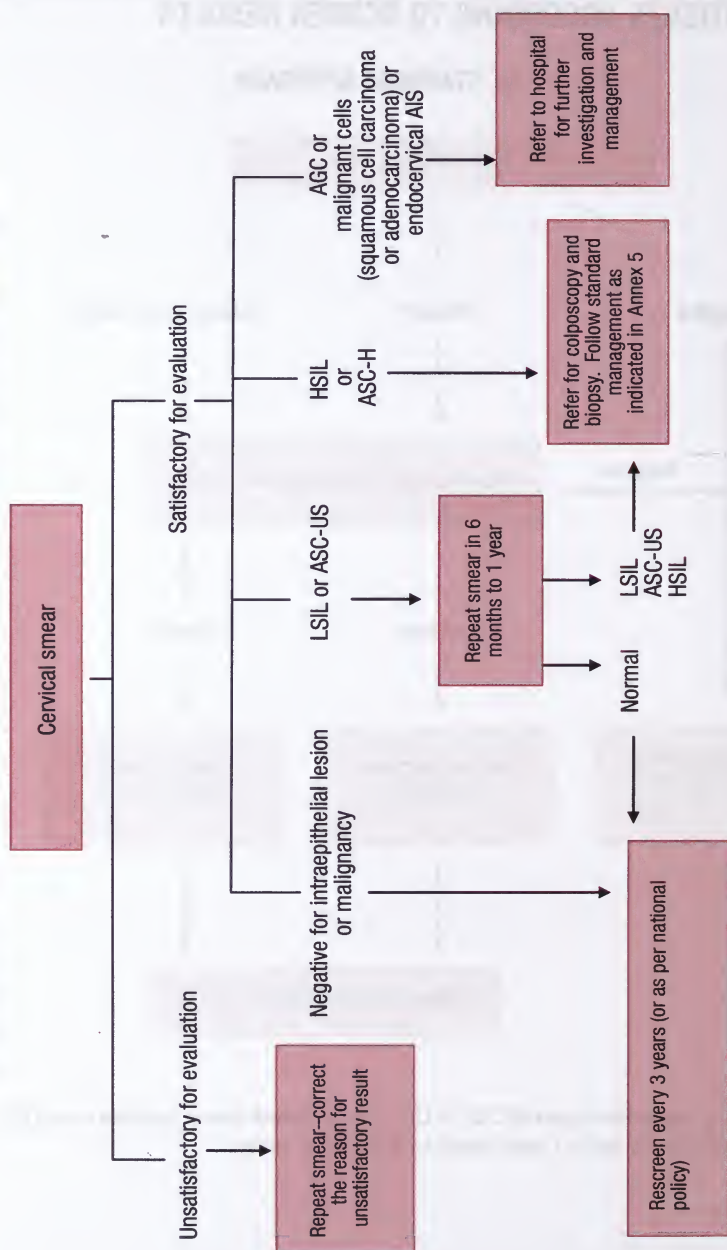


* When the Pap smear reports ASC-US or LSIL, only persistent lesions (reported on two Pap smears within 6 months to 1 year) should be investigated further.

A4

Annex 4: Flowcharts for follow-up and management of patients according to screen results

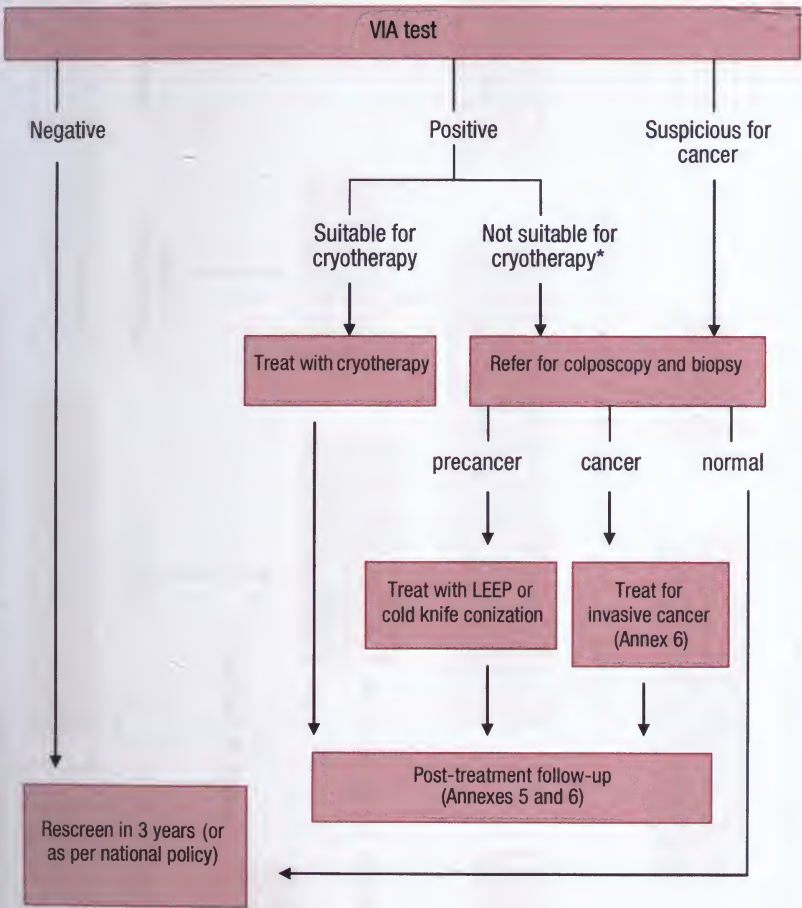
4a (example). STANDARD APPROACH BASED ON PAP SMEAR AS SCREENING TEST



LSIL = low-grade squamous intraepithelial lesion HSIL = high-grade squamous intraepithelial lesion ASC-US = atypical squamous cells of undetermined significance ASC-H = atypical squamous cells – cannot rule out HSIL AGC = atypical glandular cells AIS = adenocarcinoma in situ

* Adapted from: CHIP. *Implementing cervical screening in South Africa. Volume 1: A guide for programme managers*. Cervical Health Implementation Project, South Africa. University of Cape Town, University of the Witwatersrand, EngenderHealth, 2004.

4b. THE “SCREEN-AND-TREAT” APPROACH, BASED ON VISUAL INSPECTION WITH ACETIC ACID AS SCREENING TEST

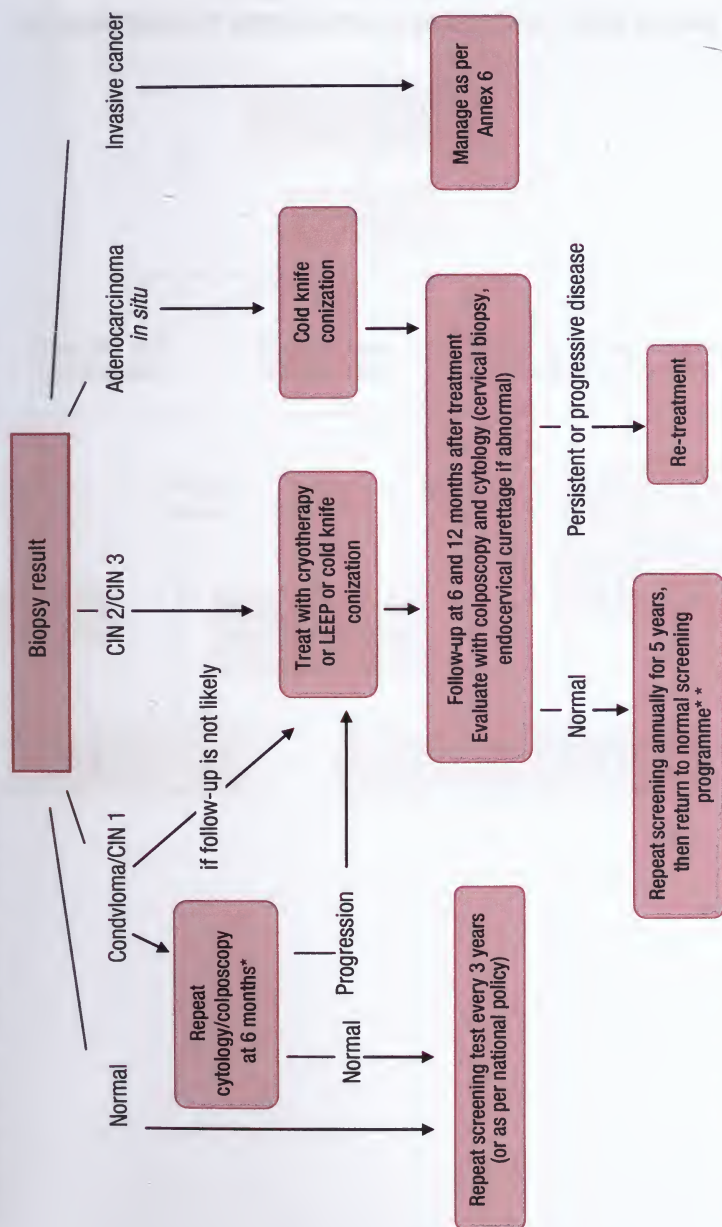


*Not suitable for cryotherapy: lesion >75% of cervical surface, extends onto vaginal wall or more than 2 mm beyond cryoprobe, or into the cervical canal beyond the probe tip. Pregnant women should also be referred.

REPORT OF THE COMMITTEE ON THE STANDARDIZATION OF MEDICAL TERMINOLOGY



ANNEX 5: STANDARD MANAGEMENT OF CERVICAL PRECANCER



* If the lesion persists, the colposcopy should be repeated every 6 months until regression or progression occurs

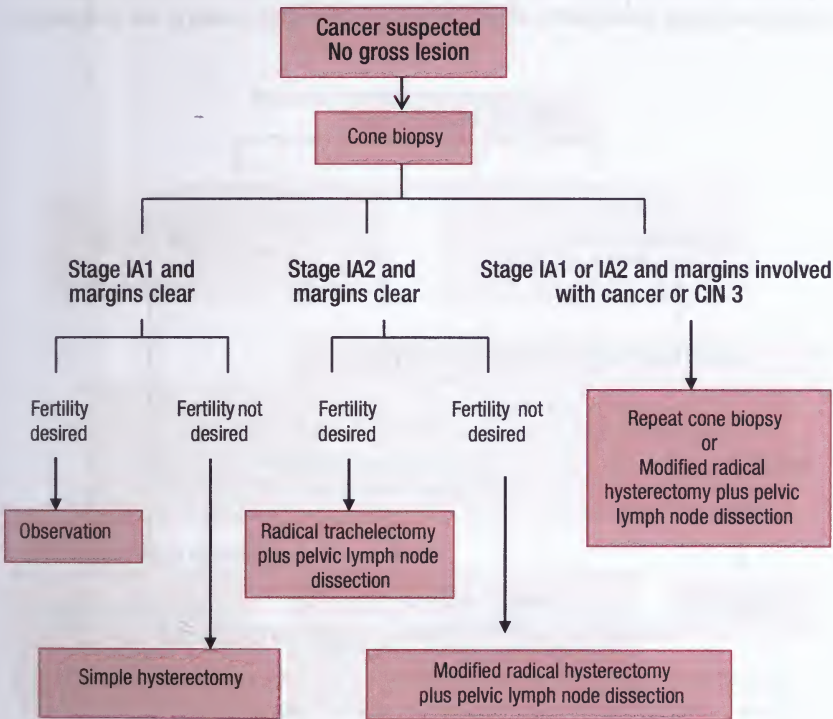
** In case of CIN1 or CIN2, return to normal screening programme after 1 year



ANNEX 6: CERVICAL CANCER TREATMENT BY STAGE

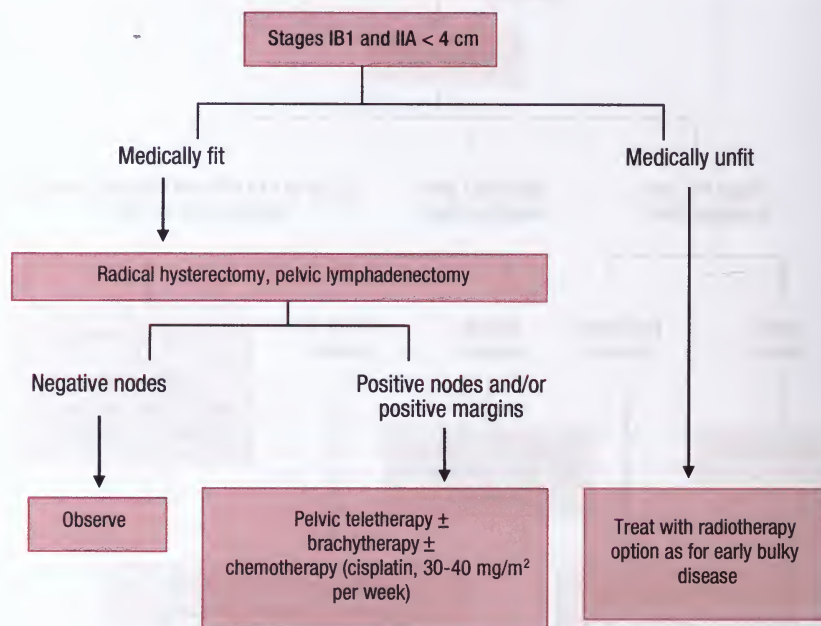
6a. TREATMENT OF MICROINVASIVE CARCINOMA: STAGE IA1 AND IA2

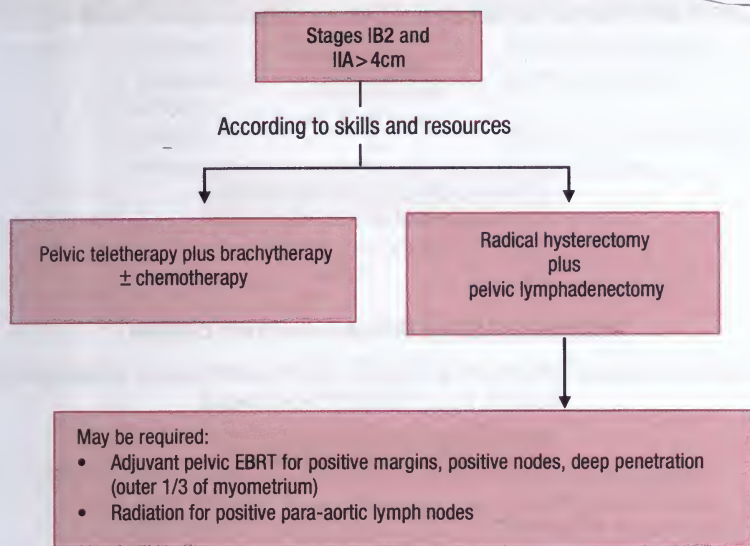
A6
Annex 6: Cervical cancer treatment by stage



6b. TREATMENT OF EARLY INVASIVE CANCER: STAGE IB1 AND IIA < 4 CM

When the tumour is more extensive but predominantly situated in the cervix, possibly with some vaginal involvement, surgical removal is preferred, except in the unfit patient.

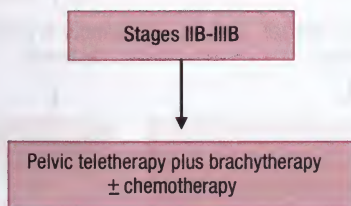


6c. TREATMENT OF BULKY DISEASE: STAGE IB2-IIIIB**Treatment of early bulky disease: Stage IB2 and IIA > 4cm**

EBRT: external beam radiotherapy

Treatment of extensive disease: Stages IIB–IIIIB

These patients are managed by radical (curative intent) radiotherapy, comprising teletherapy and brachytherapy. The role of chemotherapy has not yet been proven in developing country settings.



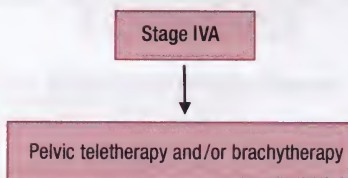
A6

Annex 6: Cervical cancer treatment by stage

6d. TREATMENT OF STAGE IV

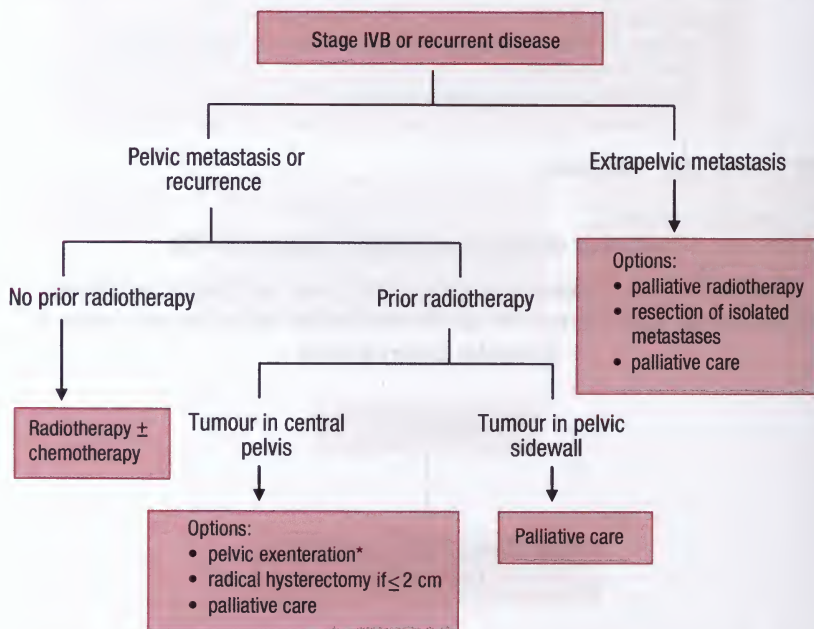
Treatment of Stage IVA

The radiotherapy to be administered depends on the condition of the patient



Treatment of Stage IVB and recurrent disease

Stage IVB (5% of cases) indicates the presence of distant haematogenous metastases and is incurable by any currently known means.



* Pelvic exenteration is infrequently used as it has major sequelae of urinary and colonic diversion, both of which are difficult to care for in developing countries, and are unacceptable to many patients when it is not possible to offer a cure.

6e. CERVICAL CANCER MANAGEMENT DURING PREGNANCY

Gestational age	Stages IA1 & IA2	Stages IB & IIA	Stages IIB, III
< 12 weeks	Immediate hysterectomy as in non-pregnant woman	Either: Radical hysterectomy with fetus in situ or Pelvic radiotherapy at 20Gy (2 weeks), with spontaneous abortion or evacuation of fetus, followed by brachytherapy	Pelvic radiotherapy with spontaneous abortion or evacuation of fetus, followed by brachytherapy
12–24 weeks	Immediate hysterectomy as in non-pregnant woman	Either: Radical hysterectomy with fetus in situ or Pelvic radiotherapy with hysterotomy at 2 weeks, followed by brachytherapy	Pelvic radiotherapy with hysterotomy at 2 weeks, followed by brachytherapy

continued next page

Gestational age	Stages IA1 & IA2	Stages IB & IIA	Stages IIB, III
24–32 weeks	Delay management until 32 weeks; at 32 weeks: amniocentesis and steroids for lung maturity if needed; then as >32 weeks	Delay management until 32 weeks; then amniocentesis and steroids for lung maturity; then as >32 weeks	Delay management until 32 weeks; then amniocentesis and steroids for lung maturity; then as >32 weeks
>32 weeks	Classical caesarean section plus hysterectomy	Classical caesarean section plus radical hysterectomy, or pelvic teletherapy plus brachytherapy after involution of uterus	Classical caesarean section Pelvic teletherapy plus brachytherapy after involution of uterus

ANNEX 7: SAMPLE DOCUMENTS ²⁹

7a. SAMPLE LETTER TO PATIENT WITH AN ABNORMAL PAP SMEAR WHO DID NOT RETURN FOR RESULTS AT EXPECTED TIME

A7

Annex 7: Sample documents

Date _____

Dear _____ (patient name),

We are writing to remind you to come in to _____ [health centre/hospital] to discuss the results of the screening Pap test you had on _____ [date of Pap smear]. We were hoping you would come in last week but since you have not returned, we send you this reminder.

Your Pap test showed some abnormal changes in your cervix (entrance of the womb) requiring another visit on your part for _____ [further diagnosis/treatment]. **(If Pap abnormality is not invasive cancer, you may add:** The changes are not indicative of cancer but, if left untreated, they may develop into cancer in the future.)

We request that you come as soon as possible in the next two weeks so that we can give you all the information, answer any questions and plan further consultations with you.

If you have any questions, please contact us at _____

Yours sincerely,

_____ [provider]

²⁹ Adapted from: CHIP. *Implementing cervical screening in South Africa. Volume I: A guide for programme managers*. Cervical Health Implementation Project, South Africa. University of Cape Town, University of the Witwatersrand, Engenderhealth, 2004.

A7

Annex 7: Sample documents

7b. SAMPLE CARD THAT CAN BE USED AS PART OF A SYSTEM TO TRACK CLIENTS WHO NEED A REPEAT PAP SMEAR

Cervical screening

Tracking card: patient recall for Pap

Name: _____

Patient number: _____

Date of birth: _____

Home address: _____

Work address: _____

Telephone number: _____

Date Pap smear done: _____

Pap smear result: _____

Date when client was asked to return: _____

NOTES:

Follow-up:

Date of repeat Pap smear: _____

Action taken if she did not return: Note sent (date) _____

Other action: _____

NOTES:

7c. SAMPLE CARD THAT CAN BE USED AS PART OF A SYSTEM TO TRACK PATIENTS REFERRED FOR COLPOSCOPY

A7

Annex 7: Sample documents

Cervical screening**Tracking card: patient referral**

Name: _____

Patient number: _____ Date of birth: _____

Home address: _____

Work address: _____

Telephone number: _____

Date Pap smear done: _____

Pap smear result: _____

Appointment for referral at _____ (name of referral site)

Date of referral appointment _____

Tracking record:

Date patient informed of referral appointment: _____

Outcome of referral: _____

**7d. SAMPLE LETTER INFORMING REFERRING CLINIC OF THE OUTCOME
OF A PATIENT'S COLPOSCOPY****A7**

Annex 7: Sample documents

To: _____ [name of referring clinic]

Name of patient: _____ Patient number: _____

From: _____ [name of colposcopy clinic]

Patient was seen in our facility on: _____ [date]

Colposcopy and biopsy were performed on: _____ [date]

Final histological diagnosis:

Management provided:

Recommended follow-up:

Thank you for your referral. Please contact us should you need further
information.

Yours sincerely,

Name:_____
Signature:_____
Date:

ANNEX 8: TREATMENT OF CERVICAL INFECTIONS AND PELVIC INFLAMMATORY DISEASE (PID)³⁰

8a. TREATMENT OF CERVICAL INFECTIONS

Therapy for uncomplicated <i>gonorrhoea</i> PLUS therapy for <i>chlamydia</i>			
Coverage	First choice Choose one from each box below (= 2 drugs)	Effective substitutes	If woman is pregnant, breastfeeding or under 16 years old Choose one from each box below (= 2 drugs)
Gonorrhoea	cefixime 400 mg orally as a single dose, or ceftriaxone 125 mg by intramuscular injection	ciprofloxacin ^{a,b} 500 mg orally as a single dose, or spectinomycin 2 g by intramuscular injection	cefixime 400 mg orally as a single dose, or ceftriaxone 125 mg by intramuscular injection
Chlamydia	azithromycin 1 g orally as a single dose, or doxycycline ^a 100 mg orally twice a day for 7 days	ofloxacin ^{a,b,c} 300 mg orally twice a day for 7 days, or tetracycline ^a 500 mg orally 4 times a day for 7 days, or erythromycin 500 mg orally 4 times a day for 7 days	erythromycin ^d 500 mg orally 4 times a day for 7 days, or azithromycin 1 g orally as a single dose, or amoxicillin 500 mg orally 3 times a day for 7 days

- Doxycycline, tetracycline, ciprofloxacin, norfloxacin and ofloxacin should be avoided in pregnancy and when breastfeeding.
- The use of quinolones should take into consideration the patterns of *Neisseria gonorrhoeae* resistance, such as in the WHO South-East Asia and Western Pacific Regions.
- Ofloxacin, when used as indicated for chlamydial infection, also provides coverage for gonorrhoea.
- Erythromycin estolate is contraindicated in pregnancy because of drug-related hepatotoxicity; only erythromycin base or erythromycin ethylsuccinate should be used.

In case of a cervical infection, the woman and her partner should be treated and counselled on condom use.

³⁰ From: *Sexually transmitted and other reproductive tract infections. A guide for essential practice*. Geneva, WHO, 2005.

8b. OUTPATIENT TREATMENT FOR PID

Single-dose therapy for **gonorrhoea PLUS** multidose therapy for **chlamydia PLUS**
multi-dose therapy for **anaerobic infections**.

Coverage	Choose one from each box (= 3 drugs)
Gonorrhoea	ceftriaxone 250 mg by intramuscular injection, or cefixime 400 mg orally as a single dose, or ciprofloxacin^a 500 mg orally as a single dose, or spectinomycin 2 g by intramuscular injection
Chlamydia	doxycycline^b 100 mg orally twice a day for 14 days, or tetracycline^b 500 mg orally 4 times a day for 14 days
Anaerobes	metronidazole^b 400–500 mg orally twice a day for 14 days

- The use of quinolones should take into consideration the patterns of *Neisseria gonorrhoeae* resistance, such as in the WHO South-East Asia and Western Pacific Regions.
- These drugs are contraindicated for pregnant or breastfeeding women. PID is uncommon in pregnancy.
- Patients taking metronidazole should be cautioned to avoid alcohol. Metronidazole should also be avoided during the first trimester of pregnancy.

In case of a PID, the partner should be treated for gonorrhoea and chlamydia, and the couple should receive counselling on condom use.

Note: Hospitalization of patients with acute pelvic inflammatory disease should be seriously considered when:

- a surgical emergency, such as appendicitis or ectopic pregnancy, cannot be excluded;
- a pelvic abscess is suspected;
- severe illness precludes management on an outpatient basis;
- the patient is pregnant;
- the patient is an adolescent;
- the patient is unable to follow or tolerate an outpatient regimen;
- the patient has failed to respond to outpatient therapy.

ANNEX 9: HOW TO MAKE MONSEL'S PASTE

What is Monsel's paste?

Monsel's paste is a thick, sticky, quickly acting compound that is used to cover bleeding areas on the cervix to stem the bleeding. It can be useful after cryotherapy, punch biopsy and LEEP. As it is a caustic product that can damage tissues if left too long, no vaginal packing should be used after application.

Ingredients	Quantity
1. Ferric sulfate base	15 g
2. Ferrous sulfate powder	a few grains
3. Sterile water for mixing	10 ml
4. Glycerol starch (see preparation on next page)	12 g

Preparation Take care, as the reaction is exothermic (emits heat).

1. Add a few grains of ferrous sulfate powder to 10 ml of sterile water in a glass beaker. Shake.
2. Dissolve the ferric sulfate base in the solution by stirring with a glass stick. The solution should become crystal clear.
3. Weigh the glycerol starch (see preparation instructions below) in a glass mortar. Mix well.
4. Slowly add the ferric sulfate solution to the glycerol starch, constantly mixing to get a homogeneous mixture.
5. Place in a 25-ml brown glass bottle.

Note: Most clinics prefer to leave the stopper of the bottle loose, to allow the mixture to evaporate until it has a sticky paste-like consistency and looks like mustard. This may take 2–3 weeks, depending on the environment. The top of the bottle can then be secured for storage. If necessary, sterile water can be added to the paste to thin it.

Label: Monsel's paste

Store in a cool place

For external use only

Use by: [day/month/year] (one year from date of preparation)

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Annex 9: How to make Monsel's paste

Preparation of glycerol starch

Ingredients	Quantity
1. Starch	30 g
2. Sterile water for mixing	30 ml
3. Glycerine	390 g

Preparation

1. In a china crucible, dissolve the starch in the sterile water.
2. Add the glycerine. Shake well.
3. Heat the crucible and its contents over a Bunsen burner. Mix constantly with a spatula until the mass takes on a thick, swelling consistency.

Note: Do not overheat, otherwise the mixture will turn yellow.

Label: Glycerol starch

Store in a cool place

For external use only

Use by: [day/month/year] (one year from date of preparation)

GLOSSARY

Note: the definitions given in this glossary refer to the way words are used in this guide. Dictionary definitions may be more general and broader.

acetowhite: area on cervical epithelium that turns white when acetic acid is applied

adenocarcinoma: cancer with gland-like characteristics; for example, cancer arising from the columnar epithelium of the cervical canal

adnexae: tissues and organs lateral to the uterus; include fallopian tubes, ovaries and ligaments

atypical cells: cells seen on a Pap smear that suggest an abnormality but are not conclusive

basement membrane: a thin layer of tissue that lies under the epithelium

carcinoma in situ (CIS): preinvasive stage of cancer involving the entire thickness of the covering layer, or epithelium, of an organ (e.g. cervix) but not penetrating the basement membrane

cervical intraepithelial neoplasia (CIN): a precancerous condition involving the covering layer (epithelium) of the cervix. It can be diagnosed using a microscope. The condition is graded as CIN 1, 2 or 3, according to the thickness of the abnormal epithelium (1/3, 2/3 or the entire thickness)

cofactor: a factor that contributes to or magnifies the effect of an agent that causes a change; usually not active on its own

colostomy: surgical construction of an artificial excretory opening from the colon

condyloma: a wart-like structure caused by low-risk HPV types; also seen in chronic syphilis

cost-effective: describes an activity or procedure that produces an adequate beneficial effect on a disease or condition in relation to its cost (in money, equipment, or time)

coverage: the proportion of all targeted persons who attend a given service in a specified time

cure rate: the percentage of a group of persons with a disease or condition who are cured by a specific treatment

cytology: the study of the structure of cells under the microscope. Abnormal findings are usually confirmed by biopsy

G

Glossary

- cytopathologist/cytotechnician/cytologist:** persons trained in the microscopic examination of smears for the presence or absence of abnormal cells
- effectiveness:** how well a treatment works to reduce a harmful condition in a target population
- efficacy:** the power of a given treatment to produce a desired effect
- efficiency:** the effects or results achieved in relation to the effort expended, in terms of money, resources and time
- epithelium (plural: epithelia):** a covering or lining, comprising one or more layers of cells; usually protective of the organ it covers
- fistula:** an abnormal passage between one hollow organ and another. With cervical cancer, fistulae may form between the vagina and the rectum, either as a result of extension of the cancer or as a late complication of radiation therapy
- fulgurate:** to use heat or electric current to destroy tissue. Fulguration is used in LEEP to control bleeding
- fungating:** describes an irregular, outward, tumour growth pattern
- gold standard:** a test considered to have the highest sensitivity and specificity; used as a measure to compare all other similar tests
- high-grade lesion:** a term used in the Bethesda classification to denote cervical abnormalities that have a high likelihood of progressing to cancer if not treated. Includes CIN2 and CIN3
- high-risk HPV types:** types of the human papillomavirus known to cause cervical cancer
- histopathology:** microscopic study of thin slices of stained tissue to determine the presence or absence of disease
- hysterotomy:** a surgical procedure to make an opening in the uterus
- immunosuppression:** reduced capacity of the body to resist attack by germs and other foreign substances, as seen in HIV-infected people
- incidence rate:** the number of new cases of a disease in a defined population in a specified time, e.g. if there are 500 new cervical cancer cases every year in a country with 5 million women, the crude (non-age-standardized) cervical cancer incidence rate is 100 per million per year, or 10 per 100 000 per year
- koilocytosis:** a condition of certain cells characterized by the presence of vacuoles around the cell nucleus

laparotomy: a surgical incision in the abdomen

menarche: the age at which a young woman has her first menstruation

metaplasia: a transformation of tissue from one type to another, e.g. from squamous to columnar epithelium

metastasis (plural: metastases): the appearance of a tumour, very similar to the original or parent tumour, in a distant organ

microinvasive cervical cancer: cancer strictly confined to the cervix, not more than 5 mm deep and 7 mm wide; it can only be diagnosed by microscopy

morbidity rate: the proportion of a population who suffer from a particular disease in a specified time, often expressed as number of cases per 100 000 population per year

mortality rate: the proportion of a population who die from a particular disease in a specified time, often expressed as number of deaths per 100 000 population per year

negative predictive value (of a test): the likelihood of not having the disease when the test is negative

neoplasia: process of new growth or tumour formation, sometimes malignant

opioid: a type of drug used to relieve strong pain, e.g. morphine

pathology: the study of disease and its effect on body tissue

peritoneum: a continuous thin sheet of tissue covering the abdominal walls and organs

persistent: describes lesions or diseases that do not disappear over a certain time

pilot study: a demonstration project in a limited population; it usually aims to provide information on performance but not necessarily on outcome (which needs to be tested in a large population)

positive predictive value (of a test): the likelihood of having a disease when a test is positive

preclinical stage: the early stage of an illness, when symptoms or signs have not yet appeared

prevalence rate: the proportion of persons in a defined population with a condition or disease at a specific point in time

primary prevention: actions to avoid exposure to the principal causes of a disease; in the case of cervical cancer, prevention of HPV infection

primary treatment: treatment that is usually tried first to attempt to cure a disease or condition

prognosis: the likely outcome of a disease (improvement, deterioration or death)

radical radiotherapy: radiotherapy with a curative intent

recurrence (of lesions, disease): the reappearance of a problem that had previously disappeared with treatment

regression: the disappearance or lessening of an abnormality

reliability or reproducibility: the extent to which a treatment or test gives the same results when repeated many times

screen-negative: result of a screening procedure that shows no abnormality

screen-positive: result of a screening procedure that shows an abnormality

sensitivity: the proportion of people who have a condition who are identified correctly by a test (true positives).

specificity: the proportion of people who do not have a condition who are correctly identified by a test (true negatives)

squamous intraepithelial lesion (SIL): precancer or abnormality of the squamous cells of the lining of the cervix. The Bethesda classification distinguishes between low-grade SIL (LSIL) and high-grade SIL (HSIL). This classification should be used only for reporting results of cytological tests

stenosis: an abnormal narrowing of a canal, which can cause health problems

survival rate: the proportion of all the people with a condition who are still alive after a certain time

syndromic approach: treatment of infection based on knowledge of the principal causes of the presenting symptoms; for example, cervical infection can be treated with antibiotics against both gonorrhoea and chlamydia, without first performing other tests to diagnose which of the two pathogens is present

triage: selection of persons, out of all those affected, for further testing or treatment

ulcerating: eating into tissue and causing a shallow crater; describes some cancers



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